Exhibit 9

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	:SUPERIOR COURT OF
	:NEW JERSEY
IN RE:	:LAW DIVISION -
PELVIC MESH/GYNECARE	:ATLANTIC COUNTY
LITIGATION	:
	:MASTER CASE 6341-10
	:
	:CASE NO. 291 CT

- - -

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

	:Master File No.
IN RE: ETHICON, INC., PELVIC	:2:12-MD-02327
REPAIR SYSTEM PRODUCTS	: MDL 2327
LIABILITY LITIGATION	:
	:

CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

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November 15, 2012

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Transcript of the deposition of AXEL ARNAUD, MD, called for Videotaped Examination in the above-captioned matter, said deposition taken pursuant to Superior Court Rules of Practice and Procedure by and before Ann Marie Mitchell, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter, Certified Court Reporter, and Notary Public for the State of New Jersey, at the offices of Riker Danzig Scherer Hyland & Perretti LLP, Headquarters Plaza, One Speedwell Avenue, Morristown, New Jersey, commencing at 10:17 a.m.

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CONFIDENTIAL DESIGNATION INDEX

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(Deposition Exhibit No. Plaintiff's-1249, Curriculum Vitae of Axel Arnaud, MD, 2 pages, was marked for identification.)

- - -

THE VIDEOGRAPHER: We are now on the record. My name is Christopher Campbell. I'm a videographer with Golkow Technologies. Today's date is November 15, 2012, and the time is 10:17. This deposition is being held in Morristown, New Jersey, In Re: Pelvic Mesh, for the Superior Court of New Jersey, Atlantic County. The deponent is Dr. Axel Arnaud.

At this time, would counsel please announce their appearance for the record.

MR. SLATER: Adam Slater for plaintiffs.

MS. CALDERON: Cheryll Calderon for plaintiffs.

MR. BALEFSKY: Lee Balefsky for plaintiffs.

MS. SCALERA: Mary Ellen Scalera for defendants Ethicon and Johnson & Johnson and the witness, Axel Arnaud.

MS. KABBASH: Maha Kabbash for defendants Ethicon, J&J and the witness, Axel Arnaud.

THE VIDEOGRAPHER: The court reporter is Ann Marie Mitchell and will now swear in the witness.

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AXEL ARNAUD, MD, after having been duly sworn, was examined and testified as follows:

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EXAMINATION

- - -

BY MR. SLATER:

Q. Good morning. My name is Adam Slater, here to take your deposition.

It's Dr. Arnaud. Correct?

A. Yes, correct.

Q. Dr. Arnaud, this is a deposition that may be used at the trial of this case, so I'm going to give you an explanation of the rules that apply to a deposition so you'll understand. Okay?

A. Okay.

Q. You have just taken an oath to tell the truth. And that's the same oath that you would take if you were sitting in front of the judge and the jury at the trial of this case.

Do you understand that?

A. I do.

Q. As you just did, it's fine for you to nod your head, but you need to also speak, because even though we're videotaping, the court reporter, Ann Marie, who is sitting to your left, is also going to record everything you say into a transcript. So it's important that you don't just nod your head but give us a clear and accurate answer and a complete answer to every question I ask you. Okay?

A. Okay.

Q. If I ask you a question that you don't understand for some reason, and it could be for any number of reasons. I, for example, might try to use a medical term and I might mispronounce it or I might ask you about something with medical terminology and it just doesn't make sense or my words just may not communicate to you. If for any reason you're unclear of what I'm asking you, just please tell me that, tell me what's unclear, and then I'll ask a more clear question, hopefully, and that way you'll be able to give truthful and

accurate testimony. Okay?

A. Okay.

Q. At different times during the deposition, attorneys may object to a question that's asked. Typically what they'll say is, I object to the form of the question. They're simply preserving their rights for the future. It's not something that is going to stop the deposition, most likely, but let the attorneys say that she has an objection or he has an objection, and then we'll proceed most likely to have you answer, or I may reask a question at times. Okay?

A. Okay.

Q. Do you have any questions of me before I start asking you questions now?

A. No. I think I'm fine.

Q. Great.

Where are you currently employed?

A. I'm currently employed in Paris, in France, and I have a European position.

Q. What is the name of your employer? Who do you work for?

A. Well, I work for Ethicon, which is part of Johnson & Johnson.

Q. What is your title?

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A. My title is EMEA medical affairs director.
Q. What does EMEA stand for?
A. EMEA stands for Europe, Middle East and Africa.
Q. I've marked as an exhibit Exhibit 1249, and that is in front of you.
Do you see the document in front of you?
A. I do.
Q. It's been represented to me that this is your current curriculum vitae, your resume of your work history and your education; is that accurate?
A. Yes, yes.
Q. I want to ask you a few questions about your background before we talk more specifically about the Prolift® and the development of the Prolift®. Okay?
A. Sure. Okay, okay. Sure.
Q. It says that before you joined Johnson & Johnson, you had done some education. You were educated. Correct?
A. A little, yes. A little bit.
Q. You received your medical degree in

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1978 from the university in Marseille in France?
A. Yes.
Q. You then, it says, were a general and digestive surgeon as of 1984. Correct?
A. Yes, yes. Sorry.
Q. And that was after you did a residency in surgery from 1977 to 1984 at the Assistance Publique-Hopitaux, hospital, in Marseille. Correct?
A. Yes.
Q. Let me ask you this.
Your practice as a general and digestive surgeon, can you explain what that means, what your medical practice was?
A. Well, my medical practice was essentially digestive surgery, because normally general surgery doesn't mean that much. When we say general surgeon, usually must be understood as digestive surgeon. So I was a digestive surgeon with some focus on colorectal, colorectal and anal surgery.
Q. What does it mean to be a digestive surgeon? Does that mean that you are operating primarily on the digestive system?
A. Yes, yes. Absolutely.

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Q. Did you do hernia surgery as part of that practice?
A. Yes, yes. That's probably the part that is the general surgery part, but...
Q. It's indicated here that you were a consultant surgeon in general and digestive surgery from 1988.
What does that mean, to be a consultant surgeon?
A. Well, this is, you know, a translation I made, you know, because the system in the US and in France may be not the same. What does that mean? It means that I was employed as a surgeon by the University Hospital of Marseille. And this employment was a lifelong employment. So unless I make something very bad, I could have stayed all my life in the -- in this organization.
Q. As a consultant surgeon, does that basically mean -- excuse me.
As a consultant surgeon, does that basically mean that if there was a patient in the hospital and the doctor's treating that patient, thought they needed a general and digestive surgeon to help them to diagnose or treat the patient, they would call someone like you in to help with the care

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of the patient?
A. Yes.
Q. Your CV indicates that after you had done your residency through 1984 and become a general and digestive surgeon, and then you were a consultant beginning in 1988, it says you then joined Ethicon France in September 1992; is that correct?
A. Yes, yes.
Q. When you joined Ethicon France, that was the name of the company?
A. Not exactly. It was called Ethnor, Ethnor. You know, it's just a translation in French of Ethicon, because the suffix "con," in French, is not so nice. So "or" means gold. And it has a better -- it sounds better.
Q. Understood.
A. So Ethnor and Ethicon is just the same.
Q. I'm going to refer to it as Ethicon for purposes of the deposition.
Is that fine?
A. Yeah, yeah. Ethnor is a word I have not heard for many years.
Q. Now, the Ethicon France that you went

to work for in 1992, that is different -- a different company from Ethicon in the United States. They're different companies, both owned by Johnson & Johnson. Correct?

MS. KABBASH: Objection.

THE WITNESS: Yes, yes. It is a -- well, I don't know exactly the legal organization, but, of course, Ethicon France is very close to Ethicon US. But it is a legally separated entity, I would say.

BY MR. SLATER:

Q. When you joined Ethicon in France in 1992, what position did you take?

A. Well, I was appointed as a director for surgical research.

Q. And it says on your resume, director research and development at Ethicon France.

And that position involved surgical research, surgical research and development?

A. Yes, yes.

Q. And am I correct that -- and I'm looking at some of the things that you did, you, in the early years, were working on hernia surgery and advancement of hernia surgery?

A. Yes.

Q. According to your CV, your resume, it says that you were director of research and development Ethicon France until 1999, and at that point you became scientific director, Ethicon Europe. Correct?

A. Yes, yes.

Q. What was your responsibility when you became scientific director at Ethicon Europe in 1999?

A. Okay. Well, the main difference, you know, in my daily job was the geographical scope. Because initially I was working for France only. But then a European organization started to be created. So when I become the scientific director, this was at the time where we created the European structure. So I continued to do the same job but on the broader scope, geographically speaking.

Q. Could you just generally tell the jury what it was that you were doing as scientific director, just a general description of what your responsibilities were?

A. Yes. Well, I was essentially in charge of the innovation, you know, innovation coming from the field. So any time a surgeon in Europe had an invention to refer to Ethicon, usually

would contact the sales reps, but then the sales reps would not know what to do about the idea, and at the end of the day, most of the time, would end up in my office.

Q. And then you would help to make decisions about whether or not the company would be interested in working with that surgeon?

A. Yeah, exactly.

Q. According to your CV, I guess the name of Ethicon changed to Gynecare Europe as of 2001? Is that what's indicated here?

MS. KABBASH: Objection.

THE WITNESS: Yes. You know, prior to this position, I was involving all aspects, all the franchise of Ethicon, while after 2001, I was working in a more focused area in a brand new company that we had created called Gynecare. So my scope geographically remained the same, Europe, but focused on Gynecare, which was part of Ethicon.

BY MR. SLATER:

Q. So when you became scientific director of Gynecare Europe in 2001, are you saying at that point, instead of being responsible for all of the Ethicon franchises or businesses in Europe, you focused down into Gynecare, this newly acquired

company?

A. Absolutely.

Q. And what was Gynecare's business at the time you took over?

A. Well, I saw the creation of Gynecare, I think this company acquired somewhere in California. And essentially, this company, when it came into Ethicon, it had two kind of products, the product for abnormal uterine bleeding and also product for hysteroscopy. But I was in Ethicon. And I started a project coming from the European field with Prof. Ulmsten in Scandinavia, which was to become the TVT®.

So, initially, this TVT® was a project I had in Ethicon. But when we acquired Gynecare, at some point, the company decided that this Ethicon project should move to Gynecare. So at the very beginning, the Gynecare company received a nice present, I would say, and that was the TVT®.

Q. So you were involved in developing this other product, the TVT®, beginning at Ethicon, and then that product was shifted to the Gynecare business and you essentially went along with it?

A. Yes, yes. You know, a couple of months after Gynecare was created, the company

decided to take the TVT® project away from the Ethicon franchise to give it to its subsidiary or, you know, I don't know how we can call this, to its franchise Gynecare, because obviously it was related to women's health.

Q. It says on your resume that you continued in the position of scientific director Gynecare Europe until 2008. So that would be 2001 to 2008.

And then in 2008, you took your current position, medical affairs director Ethicon EMEA?

A. Yes.

Q. What is your responsibility in that position, since 2008?

A. Okay. Well, in 2008, the company give me some more responsibilities, so I was in some way promoted to something broader, still in the EMEA but broader in terms of franchise. And the company gave me two positions reporting to me. And so I had the opportunity to organize my life in the way I wanted, and I decided to appoint someone whom you know probably, someone to take care of the Gynecare franchise. So that's why I appointed Dr. Piet Hinoul. So Piet Hinoul succeeded to me. I gave him

all the responsibility for Gynecare when he joined the company, because, of course, he's a gynecologist and that was perfectly fitted.

And then we have two other franchise, you know. Ethicon has Gynecare on one side, another one called Ethicon Products, which is the most important one. And for this, I had also an open position, so I appointed someone to take care of Ethicon Product. And then we have a third company called Biosurgery, Biosurgery. It's a company that is high technology company taking cake of hemostats, c-lance, very complex product, with a bright future. So I kept this for me. I kept the responsibility of Biosurgery for me.

So to summarize and to answer your question, I've been heading a small team of medical affairs and taking care personally of the Biosurgery franchise.

Q. According to your resume, from 2000 to 2005, you indicate one of your achievements was the Prolift®, which you describe as, "A system for repairing pelvic organ prolapse," and it says you "initiated and set up the project with a group of 9 experts, management until product launch, marketed worldwide." Correct?

A. Correct.

Q. I'm now going to hand you another exhibit, and we're going to start to talk a little bit about how that -- how the Prolift® came about. And I'm going to hand you an exhibit we've marked as 1250.

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(Deposition Exhibit No. Plaintiff's-1250, Press Interview Frankfort June 9, 2005, Bates stamped ETH.MESH.03923931 through ETH.MESH.03923934, was marked for identification.)

- - -

BY MR. SLATER:

Q. And I'm going to ask you just a little bit about this document, which is a "Press Interview Frankfort June 9, 2005," and was produced to us as part of your files.

So take a look at that for a moment, and then I'll have a few questions for you. Okay?

A. That was an interview of myself, I guess.

Q. Well, my first question --

A. It looks --

Q. My first question is, what is this document?

MS. KABBASH: Do you need a second to look at it first?

THE WITNESS: Yeah. If you can give me one second.

MS. KABBASH: Take a look at it.

MR. SLATER: Let's go off the video.

THE VIDEOGRAPHER: The time is now 10:35. We are going off the record.

- - -

(A discussion off the record occurred.)

- - -

THE WITNESS: Okay. I'm fine.

THE VIDEOGRAPHER: The time is now 10:36. We are back on the record.

BY MR. SLATER:

Q. Exhibit 1250 is a document that's titled "Press Interview Frankfort June 9, 2005." And again, this was produced from your documents.

Do you recognize this?

A. I do. I know that this comes from my computer, my writings, my style.

Q. You prepared this document?

A. Yes, yes.
Q. Was this something that you actually ever delivered in the press or to the media, or is it something you just prepared for some other purpose?
A. I do not remember. You know, I've not been in press interview for -- I've not given many of them. So most of the time I remember them, but this one, I cannot remember it.
Q. It's possible you did, you just don't know?
A. It's possible. It's possible it was a preparation for something that did not happen or maybe it happened, but I do not remember.
Q. The document starts off number 1, "Steps of development of" the "PROLIFT," and right under that, it says, "State of the Art in 2000."
Do you see that?
A. Yes, yes.
Q. And you basically, in describing the state of the art in 2000 in Section A, talk about the abdominal approach to repair genital prolapse, and then in section B, you talk about the vaginal approach to repair genital prolapse.
Do you see that?

A. Yes.
Q. The abdominal approach would be what's known as abdominal sacrocolpopexy?
A. Yes, yes.
Q. And about halfway down in the paragraph about the abdominal approach, you state, "This procedure gave excellent results but was somewhat too aggressive for the older patients who are numerous in this pathology."
Do you see that?
A. Yes.
Q. And at that time when you wrote this, in June of 2005, that was your viewpoint. Correct? Otherwise, you wouldn't have written it in the document. Right?
A. Yes, yes.
Q. Then in section B, with regard to the vaginal approach, you say, "The vaginal approach was and still is the most widely used procedure in particular in the oldest patients."
Do you see that?
A. Yes.
Q. And that was true as of June of 2005 when you prepared this?
MS. KABBASH: Objection.

BY MR. SLATER:
Q. You can answer.
A. Yes. Well, I think this is -- it's an overall understanding of this kind of surgery at that time, you know. I'm not sure it has changed much nowadays.
Q. And you say right after that, contrary "to the abdominal approach, a prosthesis was very seldom used."
Do you see that?
A. Yes.
Q. And when you refer to a prosthesis, you're talking about a graft or a mesh. Right?
A. Yes.
Q. Going to the next page, about eight lines down, there's a sentence that starts on the left-hand side that says, "Meshes." "Meshes were used from time to time but this was usually restricted to the worse patients, for example the ones having already had multiple recurrences."
And that was true historically?
MS. KABBASH: Do you see that language?
THE WITNESS: No, I don't. Middle of --

MS. KABBASH: That's okay.
THE WITNESS: Oh, okay. To the worse patients, for example. Yes, yes.
BY MR. SLATER:
Q. And a little further down, you talk about what you describe as the reluctance of certain surgeons to use mesh, and you say "there were two main reasons for that." And then you have the two little hyphen indented parts.
Do you see that?
A. Yes, sure.
Q. You say, the first reason, "The lack of standardized and validated procedure using mesh." And in parentheses you say, "There were basically as many procedures as surgeons."
So that was one reason. Right?
A. Yes.
Q. And the second reason, "The fear of mesh-related complications." Correct?
A. Yes, correct.
Q. And then you say, "And finding a solution to both of" those "problems was precisely the reasons why the TVM Group was set-up." Correct?
A. Correct.
Q. And then in section B of this

document, we now get to "The TVM Initiative," the transvaginal mesh initiative. Right?

A. Yes.

Q. And you state, "The TVM (TransVaginal Mesh) Group was set up in the early 2000s upon the demand of myself (Dr." Axel "Arnaud - Gynecare Europe) to a very respected expert in the field of vaginal surgery," Prof. Bernard Jacquetin (Head of the Department of Gynecology and Obstetrics in Clermont Ferrand" in "France.)" Right?

A. Right.

Q. And you say the objectives of this group were twofold. One, "develop a standardized technique for the surgical management of urogenital prolapse with meshes via the vaginal approach." And you say that was the main objective. Correct?

A. Correct.

Q. And you then say also, "Try to better understand the mechanisms of classical mesh-related complications such as vaginal erosions." And that was your secondary objective. Correct?

A. Yes. Correct.

Q. And then you give a little historical information about how this all started. And you say, "The Group TVM was originally composed of 6

gynecologist surgeons experts in pelvic floor statics and with a wide experience in the use of synthetic materials. Its first meeting was held in Nice on June 5th 2000."

So that was the first meeting of the group?

A. Yes.

Q. And at the very bottom of the document, you point out that, as the -- as time went on, the group changed and grew to nine gynecologic experts. And you say "Gynecare France was coordinating the logistics." Correct?

A. Absolutely. Correct.

Q. And you had a pivotal role in coordinating those logistics from day one. Correct?

A. Absolutely.

Q. Let me ask you this.

The idea for the TVM technique, was it Prof. Jacquetin's idea, was it your idea or did it grow through an interaction between you?

A. Well, in 2000, Gynecare had in some way changed the world of urinary incontinence, and I heard people like Jacquetin telling me, well, Axel, you have really gave -- given us the solution for urinary incontinence, so urinary incontinence is no

longer an issue for us. Now the real issue is prolapse.

So, you know, I had in France a couple of people I was in touch with who were pelvic floor surgeon. And they were coming to me, asking me, oh, could you make a mesh for me that would be cut in this way, that way, that way. So they all wanted a personal cut for the mesh. So Prof. Jacquetin wanted a Jacquetin mesh, Prof. Ix an Ix mesh. So I told these people, well, look, we as a company cannot make, you know, personal products. But what would be good would be to -- for you to work all together and try to find out a consensual procedure where you all required the same shape, the same mesh, so that we could, as an industry, support you and eventually offer that to the rest of the world.

So, you know, if I try to summarize, the context was incontinence, everybody was happy about Gynecare saying, well, what you did is fantastic. So now, could we do the same thing in prolapse, which meant introducing, not a sling like in incontinence, but a mesh for prolapse, because prolapse is a broader anatomical issue, so a sling cannot cure a prolapse probably.

So I approach Jacquetin and I said, well, look, you are the -- you have been using meshes forever. He had probably used more meshes in more than 1,000 patients. He is probably the one most experienced guy at that time. He was at that time the most experienced guy in meshes. So I talked to him, and I said, why don't we try to set up a working team, a team that would work and try to improve the surgery of prolapse, which at that time was not very, very efficient.

MR. SLATER: Move to strike.

BY MR. SLATER:

Q. Just what I did is --

During the deposition, I may at some point ask you a question that I think is very narrow, and you might talk about other things I didn't ask about. And I'm just preserving my rights, just like an attorney would object, I'm preserving my rights.

Let me ask you this question as a narrow question. My question -- my next question is -- well, rephrase. Withdrawn.

If we look at the document, a little bit further down on the third page, you talk about a preliminary study that was done with the TVM

technique, and you talk about some results from that technique.

And one of the things you say is that there was mesh exposure in that early study from 2002 to 2004 of 12.3 percent. Correct?

A. That's correct.

Q. And mesh exposure is defined as what?

A. Sorry?

Q. What is mesh exposure as used here? What does that mean?

A. Well, mesh exposure is a word that -- a design condition where, when you perform the vaginal examination of the patient, you find in the vaginal wall a loss of substance. And you can see the mesh in the depths of this loss of substance.

Q. On the next page, this is now the last page of this document, there's a discussion of something called shrinkage. And we're going to put that up on the screen.

And it says, "Shrinkage is due to an excessive scarring process. Even if most of the time it is asymptomatic, in a few cases it led to vaginal distortion impacting the sexual life. Thus, the procedure must be used cautiously in sexually active women."

Do you see that?

A. Yes, I do.

Q. And that was something that you learned over the years as the TVM Group was developing the TVM procedure. Correct?

MS. KABBASH: Objection.

THE WITNESS: Well, at least it was something we knew in -- at this time, you know. Yes, yes. Well, shrinkage is something that's not absolutely new at that time, you know, because people like Prof. Jacquetin have been using meshes for a very long time, you know. So they have already had a good knowledge about what were the possibility and what were the risks of using meshes.

BY MR. SLATER:

Q. We're now going to go to the next document, and it's marked as Exhibit 1251.

- - -

(Deposition Exhibit No. Plaintiff's-1251, E-mail dated 29 Jan 2002, with attachment, Bates stamped ETH.MESH.03909826 through ETH.MESH.03909829, was marked for identification.)

- - -

BY MR. SLATER:

Q. I'm going to send it over to you.

Exhibit 1251 is an e-mail that you wrote on January 29, 2002 to Laura Angelini. And the subject, "Confidential/Project TVM."

Who is Laura Angelini who you wrote this e-mail to in January of 2002?

A. Well, Laura Angelini was the vice president of marketing in -- for Gynecare in Europe. And she had been my partner, my commercial partner, during the development of TVT®.

Q. And you attached to this e-mail a document that you titled "Project TVM (TransVaginal Mesh.)" Right?

A. Yes.

Q. And is this the first time that you formally proposed this project to the marketing arm of Gynecare?

A. Well, if you can give me one second, just to --

Q. Certainly.

A. Okay.

Q. Is this the first time that you formally proposed the TVM project to the marketing people within Gynecare?

MS. KABBASH: Objection.

THE WITNESS: I think so.

BY MR. SLATER:

Q. Okay.

A. I think so.

Q. And in your e-mail to Laura Angelini, after you tell her, "Please find attached a draft of the Project TVM," you point out that -- a little further down you talk about prolapse surgery, and you talk about the fact that this procedure indeed "is a triple operation performed in a single operative session."

Do you see that?

A. Yes, yes. No, I...

Q. You point out, "The procedure is certainly not as revolutionary and 'sexy' as Ulf's procedure."

That would be the TVT®. Right?

A. (Witness nods head.)

Q. "But I think we could reach a comparable level of success since the need for a gold standard is even greater than it was for TVT." Right?

A. Right.

Q. And I want to understand, the TVM

procedure is a method for the treatment of pelvic organ prolapse. Correct?

A. Yes.

Q. It was intended to be an alternative procedure that gynecologic, urogynecologic or urologic surgeons who would treat prolapse could utilize as an alternative as compared to the procedures that were available at the time.

Is that a fair statement?

A. Yes, yes.

Q. And your hope was that surgeons who were gynecologists or urogynecologists or urologists who treated prolapse would be interested in this technique as compared to the other techniques that were currently available, like what we talked about in that prior document, abdominal sacrocolpopexy, vaginal repairs and the like. Correct?

MS. KABBASH: Objection.

BY MR. SLATER:

Q. The intention was to offer them an alternative to those procedures. Correct?

A. Yeah, a better alternative. An alternative that would lead to much less recurrences than the technique without meshes, which were not at all satisfactory. You know, the intent was with the

TVT®, what we brought was a procedure that gave good results in 90 percent of the cases. And that was very different than what was existing without the sling. Without the sling, the gold standard was the Burch procedure. All the surgeon knew that the Burch procedure was a very poor gold standard, because the rate of success was very low, and if you would wait, with time, the rate of success would be even lower. So the sling brought a dramatic improvement in the efficacy and, more importantly, in the efficacy over time, over time, on the long term. So the purpose of the TVM procedure was exactly the same, you know, bring more success in a short term but also the guarantee of a long-term success.

MR. SLATER: Move to strike from "with the TVT®" forward.

BY MR. SLATER:

Q. Your goal was to try to develop a better alternative, that was your hope, to the existing procedures. Correct?

A. Yes.

Q. Your expectation was that if somebody was an experienced pelvic reconstructive surgeon, a urogynecologist or a gynecologist or a urologist,

that they would be able to understand this procedure, they would be willing to understand how it's done, and with some training, be able to perform it. That was again your hope. Correct?

A. Yeah. My hope was to offer a new procedure that would be more efficient in term of recurrences than the existing ones.

Q. And you then say -- let's go to the actual "Project TVM" document. You say that, with regard to the medical background and rationale, "For a manufacturer of medical devices, surgery for genital prolapse is an attractive market."

Do you see that?

A. I don't see it, but I can understand it.

MS. KABBASH: I want to make sure every time Mr. Slater asks you about language, that you look for that language.

THE WITNESS: Yes.

MS. KABBASH: Okay?

THE WITNESS: Okay. Okay.

BY MR. SLATER:

Q. Do you see what I just read?

A. Yes, yes.

Q. And what you were saying to the

marketing person who you forwarded this to is that you think that this is a market where the company can successfully market this procedure and profit. Correct?

MS. KABBASH: Objection.

THE WITNESS: Yes.

BY MR. SLATER:

Q. You then say, "Nevertheless, it is a difficult area for two main reasons."

Do you see that?

A. Yes.

Q. And the first reason you say, reason A, "The use of an implant such as a mesh is not established as a standard. Most of the current procedures do not involve the use of any implantable materials."

That's one of the reasons you stated why this could be a difficult area. Correct? That's reason A. Right?

A. I'm lost, I'm lost.

Oh, yes. Okay, okay. A.

Q. And then a little further down you have a little B, the second reason why you say this is a difficult area. And you say, "With regard to surgical techniques, there is no gold standard."

That's what you wrote. Correct?
A. Yes.
Q. And you then, at the very bottom of that paragraph, you basically say that you're looking to develop what you call a gold standard technique, and you describe that as "a technique which is sufficiently simple, safe, reproducible, logical and effective that it will attract the majority of the non-experts."
Do you see that?
A. Yes.
Q. And when you refer to the nonexperts, you're talking about people who are surgeons but may not be the top surgeons like a Prof. Jacquetin. Correct?
A. Of course, yes.
Q. And, again, you want to be able to market not just to somebody like a Prof. Jacquetin, but you also want to be able to market to the nonexperts, because, of course, you can market more products if you can market not just to the very top doctors but also to those who are what you call the nonexperts. Correct?
MS. KABBASH: Objection.
THE WITNESS: Yes, yes. Of course,

this is the intent. You know, this is my intent. I'm not saying at that time we were going in the future, so no visibility what we were going to end up with, would that be a very simple procedure, would that be a very complex procedure. But at least my intent, you know, as a company was to offer a procedure as simple as possible, as safe as possible, as efficient as possible. But that was just a project.
BY MR. SLATER:
Q. Understood.
Then on the next page you give an overview of the project. And you say, phase 1 is to "Identify an expert" to "Design the procedure." And the expert you identify is Prof. Bernard Jacquetin in Clermont-Ferrand, France. Correct?
A. Yes.
Q. You say, "He is the undisputed leader of vaginal surgery in France and a well recognized international expert."
That's one thing you said about him. Right?
A. Correct.
Q. "He has a unique experience of over 1,000 prolapse repairs using a mesh." Right?

A. True. Yes.
Q. "He knows exactly what other international experts do." Correct?
A. Yes.
Q. "He is a very good friend of us," and you talk about that he helped to launch the TVT® in France. Correct?
A. Yes.
Q. You call him "a very reliable and knowledgeable person." Correct?
A. Absolutely. Correct.
Q. And you say, you say, "Most importantly, he showed me a procedure which I believe presents all the qualities to become a gold standard."
And that's your reasoning for why you thought he was the right person to work with. Correct?
A. Yes.
Q. Would it be fair to say that from that point forward, the description of your respect for him and the reasons why you thought he should be the expert at the lead of the project remain the same. You always held him in such high esteem. Correct?

A. Yes.
Q. And you always felt that his opinions with regard to TVM and ultimately the Prolift® should be respected because you held him in such high esteem. Correct?
MS. KABBASH: Objection.
THE WITNESS: Yes, yes. Of course.
BY MR. SLATER:
Q. One of the things you did, and the people who worked with him as this project went on did, is to rely on his input and take that into account as the project went forward and as the Prolift® was launched and beyond. Correct?
A. Yes, that's correct. You know, I rely on him because he's an honest person and he's a real expert. He has spent all his life doing only vaginal surgery, nothing outside of that scope. So he's very reliable.
Of course, I was not only listening to one person. I had a group of ex -- other experts. And if Jacquetin -- I have not a blind belief in what Jacquetin was saying, you know. I had sufficient experience, too, in my job for innovation, you know, to understand that one single person, even the most reliable person in the world,

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can be wrong. So I used to say, if you ask one person, he is a great expert, you are sure 80 percent. If you ask two, we'd say that's very good, you are sure 90 percent. If you ask a third person who share the same opinion, you are sure 100 percent.

So, of course, I was not blindly listening to what Jacquetin was saying, but I had other -- other voices talking to me, of course.

Q. Understood.

My question really is just that you, because of the things you described about him, felt he should be the expert to lead this project. And as time went forward, his input continued to be a very important consideration for you and the company as you went forward with this project, launched the Prolift® and beyond. Correct?

A. Yes.

Q. You then talk about the procedure, which would involve, at that point, it was three steps, a vaginal hysterectomy, a cystocele or anterior repair, meaning if the bladder was dropping into the vaginal, a rectocele or posterior repair if the rectum was dropping into the vagina. Correct? It was, at that point, thought of as three parts.

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Correct?

A. Correct.

Q. And you talked about designing the products, and that's where you describe the mesh and a system to fix it on both sides.

And, ultimately, since you had this procedure, you needed the materials to execute the procedure, and that would be the mesh and the instruments. Correct?

A. Yes.

Q. And we go to the next page. Phase 3 of the project is to "Spread the technique locally" and have a localized clinical trial with what you proposed, to have Prof. Jacquetin do a localized study with patients at his hospital. Correct?

A. Yes.

Q. And the hope was to validate this by getting some good early results with Prof. Jacquetin to help to support this project. Correct?

A. Prof. Jacquetin and the group.

Q. And the group he was working with?

A. The TVM Group.

Q. And then you talk about "Observational clinical trial." And you say that, "This would call for an observational study

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performed in a single center (Pr Jacquetin)," you have in parentheses, "in order to generate reliable clinical data as soon as possible."

That's what you wrote there. Correct?

A. Yes.

Q. You say, "This also implies an aggressive product development as the clinicals could hardly" start "before a specific product is available," meaning we need to get this product developed so we can then give it to the doctors to do this study, this clinical study, with the product. Correct?

MS. KABBASH: Objection.

THE WITNESS: Well, that's not exactly what I mean. You know, I know that if you want to start a clinical trial, you can start it with product that are -- with prototypes, let's say. Product that's not -- that are different from the one that's going to be put on the market but are similar in some way, but they are not already approved for marketing. You can start a clinical trial with a product that's not yet approved.

So that's what I meant. But usually, if the product is not approved, then the burden, the

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administrative burden, it takes some time. It's more complex. So that's what I meant, you know, by saying it could hardly start before a specific product is available, because, you know, the administrative burden is more important.

BY MR. SLATER:

Q. And then a little further down, you say, "I do believe that long term clinical data are unnecessary for a market launch of this procedure/products."

Do you see that?

A. Yes.

Q. So what you're saying is you don't think that long-term data would be needed in order to support going to market with the product. Correct?

A. Correct.

Q. And then you say, "Indeed, there would be very little concern about the safety."

That's one thing you said. Right?

A. Sorry, I don't understand.

Yes, yes.

Q. And you say, "And sufficient good sense evidence that the procedure would work."

That's also what you said. Right?

A. Yes.
Q. And you're saying that on the part of the surgeons who this would be marketed to. Correct?
A. Sorry?
Q. You're saying that the surgeons that you would be marketing this procedure and this product to, you would not need long-term clinical data in order to get them to use the product. Right?
MS. KABBASH: Objection.
THE WITNESS: Yes.
But I can explain on that, you know.
BY MR. SLATER:
Q. I certainly might ask you that in a little bit. I just want to get through this a little bit.
In fact, when the Prolift® eventually was launched, at that time there was not long-term data with the actual Prolift®. Correct?
MS. KABBASH: Objection.
THE WITNESS: Yes. Of course, because it was a brand new product. So you cannot have long-term data with a brand new product. But there were data on the long term for meshes that

have been used by people like Jacquetin, for example, have been using meshes forever. So we had a good idea of what was the long term with meshes.
MR. SLATER: Move to strike from "but" forward.
- - -
(Deposition Exhibit No. Plaintiff's-1252, E-mail chain, top one dated 09 Jul 2002, Bates stamped ETH.MESH.03909986 through ETH.MESH.03909990, and Deposition Exhibit No. Plaintiff's-1253, PowerPoint, "The Use of Meshes in Vaginal Prolapse Repair," 42 pages, were marked for identification.)
- - -
BY MR. SLATER:
Q. I'm going to hand you the next two exhibits, which actually go together. Exhibit 1252 is an e-mail you wrote July 9, 2002. So we're going ahead about six or seven months. And Exhibit 1253 is the PowerPoint presentation you referred to in that e-mail titled "The Use of Meshes in Vaginal Prolapse Repair."
Do you need a moment to look at those?

A. Maybe the e-mail, because the presentation --
MR. SLATER: Go off the video.
THE VIDEOGRAPHER: The time is now 11:07. We are now going off the record.
- - -
(A discussion off the record occurred.)
- - -
THE VIDEOGRAPHER: The time is now 11:10. We are back on the record.
BY MR. SLATER:
Q. I've put up on the screen what we've marked as Exhibit 1253, which is the presentation you referred to in your July 9, 2002 e-mail. Correct?
A. Correct, correct.
Q. And you said in the e-mail, "Please find" -- you're writing to Paul Parisi.
Who is Paul Parisi?
A. Paul Parisi is someone that was working in Somerville, in the Ethicon headquarters. And I believe at that time he was a professional education guy.
Q. You wrote to Paul Parisi and said --

he had given you some information in the e-mail earlier with regard to the mesh. And you say, "Please find attached the presentation I made at the European Sales Meeting in Sardinia which could be interesting for you. Best regards." Right?
A. Yes, yes.
Q. Just to jog your memory, at that point in time, was Paul Parisi in marketing?
A. I don't know. I know Paul has been probably marketing at some point, in prof ed at some other point, but as prof ed, he is part of marketing maybe.
Q. Just a little further down in the e-mail, the e-mail he had last written to you, when he signed off, the signature is "Paul Parisi, New Product Development Specialist, Gynecare Worldwide, a division of ETHICON, a Johnson & Johnson company."
Does that help to refresh your memory of what he was doing at that time?
A. Yes. New product development specialist, probably someone in the marketing, but I would not be -- I cannot speculate on that. I don't remember, you know. It's not a title that is very common in the company, at least.
Q. Well, you provided this presentation

regarding the use of meshes in vaginal prolapse repair to the European sales meeting probably sometime recent before July of 2002.

Why did you give that presentation to the salespeople in Europe?

A. Well, I gave this -- I don't remember. I gave this presentation because, of course, someone asked me to do so. But what is the reason, the exact reason, I don't remember.

Q. And it actually says on the PowerPoint, "Sardinia, July 3rd."

So that's likely the day you make this presentation. Correct? July 3, 2002?

A. Yes, probably.

Q. If you could turn to the third page of that document, it's titled, "The Pathology." Where it says "The Pathology," it talks about the cystocele.

And what is a cystocele?

A. Well, a cystocele is a prolapse of the bladder wall in the vagina.

Q. Then it says, "Uterine Prolapse, Vaginal Vault Prolapse."

What is that?

A. Well, you know, a prolapse is

always -- well, can have three component, because there are three area in the pelvis, the anterior, the medial one and the posterior. So anteriorly, you have the urinary apparatus. So it's the bladder essentially. So it could be cystocele. And then in the medial part, it is the uterus. It's a genital tract. The uterus, if you still have it, and the vaginal vault, if you do not have a uterus. And the posterior means the rectum, the digestive tract.

Q. And the diagram to the left, the illustration shows in simple but accurate terms the anatomy of the female pelvis and the part of the anatomy that's involved in pelvic organ prolapse. Correct?

A. Yes, yes. The intent is to show the three areas.

Q. If you could, turn forward about six pages or seven pages. There's a page with the title at the top, "Are there any scientific proof that mesh would reduce the recurrence rate?"

And when you talk about a recurrence rate there, you're talking about where somebody has surgery to repair a prolapse and then a prolapse occurs again in the future. Correct?

A. Yes.

Q. Would that include, for example, if a woman had a cystocele and there was a repair of the front part of the vagina, if that were to happen again in the future, that would be a recurrence. Correct?

A. Yes.

Q. If the woman had a cystocele and there was a repair in the front part of the vagina for the cystocele, but she were then to get a rectocele in the back part of the vagina, would you also call that a recurrence?

MS. KABBASH: Objection.

THE WITNESS: You know, it's a recurrence of the prolapse. It's not a recurrence of the treated side, but it's still a recurrence -- for the patient, it's a recurrence of the prolapse. I don't think the patient makes a difference between both. So what is -- for the patient, the patient, the result is the same, whether it recur where it has been repaired or whether it has recurred in another area.

BY MR. SLATER:

Q. When you talk about the recurrence rate of whether a recurrence had happened again, at that point in time, were you talking about

anatomically simply measuring whether or not the organ had dropped to a certain level where you would say, oh, there's a prolapse again? Was it an anatomic measurement?

A. No. At this time, in this presentation to the sales reps or to the sale force, it's not an attendance of experts, you know. I'm talking generally. I'm generally speaking about recurrence.

Q. Understood.

I'm just asking, at that point in time, was your understanding when you talked about recurrence, were you talking about an anatomic recurrence, meaning that the anatomy had dropped to a certain point so that it would measure out and you would say, okay, that's a recurrence based on the measurements?

MS. KABBASH: Objection.

BY MR. SLATER:

Q. Is that what was meant by recurrence at that time when you used the term?

A. Well, it's difficult to say what I had exactly in mind, you know, but recurrence of a prolapse is just same as a recurrence of a hernia, you know, something is back again and the result is

not optimal.
Q. When you asked the question in this PowerPoint, "Are there any scientific proof that mesh would reduce the recurrence rate," you point out, there are "No randomized studies."
So those types of clinical trials had not yet been done. Correct?
A. Yes.
Q. And you say, there are "strong analogies with other areas such as: Inguinal hernia" or "Incontinence."
So you're drawing an analogy to those other situations. Correct?
A. Absolutely, yes.
Q. And then you basically say, as of 2002, July of 2002, from your perspective, "We can realistically anticipate that meshes are the future of prolapse surgery."
That was your viewpoint at the time. Correct?
A. Yes.
Q. And then the PowerPoint continues through the requirements for the mesh, and there's a page that actually is titled "The 5 Essential Product Requirements." And you point out five

things that you describe as essential for the mesh product. Correct?
A. Correct.
Q. And number "1. Must resist infection as much as possible. 2. Must incorporate the surrounding tissues. 3. Must be histologically well tolerated. 4. Must be soft." And "5. Must not shrink."
That's what you felt were essential requirements for the product you were trying to develop. Correct?
A. Yes.
Q. And if you could flip to the next page, there's a discussion of product requirement 1, which says, "Must resist infection." Right?
A. Yes.
Q. And you say, "Why" does it need to resist infection? Because there's a "high risk since" the "vagina is not aseptic."
What does that mean?
A. Well, that's a -- that means that usually implants, generally speaking, what you put in the human body, are put through an approach which is aseptic. The aseptic is preferred. For example, you put a heart valve, you do not go through

something that is not aseptic.
But for the first time in the history, we were -- we were introducing meshes in the human body through the vaginal cavity, which is not an aseptic cavity. It's like the mouth, the vagina. There are bacteria, normally speaking. So if you go through the vagina, there are bacteria. And even if you clean perfectly, you know, it's not considered an aseptic approach. It's a septic approach.
It would be the same, if, for example, you would introduce a mesh through the mouth. And this is done in dental surgery. I say it is a unique situation. It's not exactly the word, it's a unique situation. It also occur in dental surgery where they use meshes for other purpose.
So what I mean there is it must resist infection, and this is a product requirement, which is even more important in vaginal approach than in inguinal hernia or incontinence -- or not incontinence, or in incisional hernia, for example.
Q. So you knew that when the mesh would be introduced through the vagina, that it was foreseeable that it could be contaminated with

bacteria, so you wanted a mesh where it would help -- it would allow the body to help resist infection from the contamination; is that correct?
A. Yes, yes.
Q. And a little below that, you talk about the interstices and micropores, and you're basically saying the size of the openings in the mesh need to be big enough so the body's defenses can get in there to try to fight the bacteria.
Is that a simple understanding of that?
MS. KABBASH: Objection.
THE WITNESS: Not exactly. So I made this presentation very often, and people have been very -- there have been a lot of confusion about that.
It's not a matter of pore size. It's a matter of the mesh must not offer extremely small location where the bacteria can go and get protected from the macrophages. So this slide is introducing a second slide which says, look, if it is monofilament, if it is monofilament, there is no space for the bacteria to go. If the mesh is made of multifilament, then you have in between each filament tons of spaces where the bacteria can go,

stay forever, because the macrophages cannot go and catch them.
BY MR. SLATER:
Q. Let's go to the next page.
And on the next page of the PowerPoint, you actually have pictures of, on the top, some multifilament meshes. Correct?
A. Yes. On the top left. Yes. Okay.
Q. All three of them are actually multifilament --
A. Not the last one, not the GoreTex.
Q. The bottom picture is what?
A. The bottom -- the bottom picture is a monofilament.
Q. Which mesh is that?
A. I don't know, but I believe it's one of ours.
Q. Let's go to product requirement 2 where you describe it a little bit more. And you say, it "must incorporate to the surrounding tissue," because there's "less risk of rejection in incorporated instead of encapsulated." Right?
A. Yes.
Q. And for that you say the pores must be at least 75 microns in size so that blood vessels

can grow in and so that tissue can grow in and incorporate the mesh with the body. Correct?
A. Correct.
Q. And that's the purpose for that 75 micron?
A. Yes.
Q. Correct. Okay.
Let's go to product requirement 3. It says, "Must be well tolerated...in order to limit the fibrosis."
What do you mean by that?
A. Well, very simply, if you put -- amount of biomaterial you can put in the human body, you cannot put all the material that existed in real life. Some of them are called biomaterial because they are well tolerated -- they are better tolerated in the -- by the human body than others.
So first selection is biomaterials. Now, among biomaterials, the matter that can enter a human body, some of them initiate more inflammation than some others. So what I mean by this was, well, let's try to find -- we need a material that is eliciting as little inflammatory response as possible.
Q. Did you learn --

Well, did you know then or learn as you went on that different people would have different responses, their bodies would have different responses so the inflammation would be different from patient to patient?
A. Well, of course, because this is a general principle, you know, not all human being are the same, so it can happen that someone tolerate something better than another.
Q. Did you ever make any effort, beginning from the beginning of the project right through, even after the Prolift® was launched, did you ever make an effort to try to figure out who are the people who would have a high response, who would have a lot of inflammation and might be at more risk as opposed to people who would have less inflammation? Was there ever any effort to try to identify those patients?
MS. KABBASH: Objection.
THE WITNESS: Well, this is -- this is somewhat idealistic. You know, implant have been used in human body forever. And at that time, and still nowadays, it's very unlikely that we can predict by any kind of testing what will be the reaction to an implant, you know, suture or implant,

for example, that have been used forever. And, you know, in the huge majority of people, suture well tolerated, but sometime a suture might be less tolerated by someone. But there is, to my best knowledge or at least at that time, there was absolutely no scientific testing, you know, that could say, this person is going to react, this person is not going to react. And if such, it is my assumption, if such kind of testing would be developed one day, that would require, you know, research that would come from, you know -- from privatory research, not from a company perspective.
BY MR. SLATER:
Q. All I'm asking is, because you said obviously this is the -- at this point in time is the first time meshes were being placed through the vagina, did your company make any effort to try to research, to try to figure out which women might be at more risk for a high level of inflammation so you'd have ability to warn them or warn doctors to look out for those women?
MS. KABBASH: Objection.
BY MR. SLATER:
Q. Was an effort made to do that?
A. Well, what you need to know is that

we had a huge experience of meshes being placed into the vagina, thousands of them, due to the TVT® experience. So the TVT® experience taught us a lot. And this project would never have happened if we would not have had the precedent of the TVT®. So the TVT® taught us infection is not an issue, because in TVT® there is basically no infection. Infection is not an issue. And tolerance of meshes is very good. So that's -- that was the basis we had at that time.

MR. SLATER: Move to strike.

BY MR. SLATER:

Q. My question is simply this.

Did your company make any effort to actually try to determine or fund any research in any way to figure out which women would be the higher responders and would have more inflammatory response to the mesh that you were proposing to put in through the TVM and the Prolift®? Specifically to that, was any effort made?

A. Well, we certainly made efforts in preclinicals to look at the tolerance of all this material. We, as Ethicon, have a huge database of tolerance of biomaterial, because probably we're one of the most famous company in the world in term of

biomaterial. So we were using a material called polypropylene. Polypropylene has been used in the human body for over 30, 40 years. It's the main suture used in cardiac surgery. So we have never felt it was necessary to perform this kind of test for the sutures. It was not necessary for the slings. So this kind of testing was not considered as being essential.

MR. SLATER: Move to strike.

BY MR. SLATER:

Q. After you talk about product requirement 3, that the mesh, "Must be well tolerated...in order to limit the fibrosis," you say, the "Theory" is, if you have a "Good material" with a "Minimal amount" of the material, that would be your best chance to limit the fibrosis. Correct?

A. Yes.

Q. Why did you want to limit the fibrosis?

A. Well, of course, we want to limit the fibrosis because the vagina is a mobile structure. So fibrosis mean lack of flexibility, extensibility. So it's normal that you try always to limit the fibrosis.

Q. Did you have a specific concern that

if you had fibrosis and stiffness of the implant over the course of time once implanted in the woman, that that could have a negative impact on her function?

A. Yes, of course. It is obvious for a surgeon that if you perform something in the vaginal cavity and this would lead to extensive fibrosis, this is likely to create some problem in a sexually active woman. It's rather obvious.

Q. Go to the next page, please.

We're going to go to the next product requirement 4. You stated that the implant "Must be soft." And then you say that's "In order to preserve the sexual life, it is essential to: preserve the suppleness of the vagina" and "avoid irritating spikes." Correct?

A. Yes.

Q. When you say it must be soft, are you saying it must be soft when it goes in only or are you saying it must remain soft over the course of time?

A. Well, of course, ideally it should remain soft over the course of time. But this is something we know is -- is a little bit illusory because -- I don't know if that is the correct word

in English, it's an illusion, because after a couple of days, you know, the fibroblasts invade the implant. And after some times, you know, the implant cannot behave as it would have behaved in the box, you know.

So it's -- when I say the softer, I mean, well, don't use a very stiff one initially, because it goes against your interest, against interests of the patient. And when I say -- well, the softer the better initially. But I have no -- I have no, you know, vision that after a year, the implant will still behave in a very elastic and perfect way.

Q. Let's go to the next page.

Product requirement 5 that the mesh "Must not shrink." And you say that's because it "Could deteriorate the repair and be painful for the patient."

That's what you wrote in this PowerPoint. Correct?

A. Yes.

Q. Then you say the "Theory" is, "The reasons why meshes shrink are unclear. Shrinkage is part of the healing process and cannot be avoided." And then you say, "Shrinkage can be minimized by

reducing the inflammatory reaction." And your thought was you could do that with a "well tolerated material" with "large pores." Correct?

A. Yes.

Q. So product requirement 5 was the mesh "Must not shrink," but on the other hand, you knew that shrinkage was going to happen and the mesh would shrink. Correct?

A. Yes.

MS. KABBASH: Objection.

MR. SLATER: Let's go off. He has to change the tape.

THE VIDEOGRAPHER: The time is now 11:33. This is the end of Disk Number 1. We are going off the record.

- - -

(A recess was taken from 11:33 a.m. to 11:52 a.m.)

- - -

THE VIDEOGRAPHER: The time is now 11:52. This is the beginning of Disk Number 2. We are back on the record.

- - -

(Deposition Exhibit No. Plaintiff's-1254, E-mail chain, top one

dated 19 Sep 2002, Bates stamped ETH.MESH.03801777 through ETH.MESH.03801779, and Deposition Exhibit No. Plaintiff's-1255, Meeting Minutes Anterior TVM (Porthos) Chartering Concept -> Feasibility Kick of meeting 14th April 03, Bates stamped ETH.MESH.03801569 through ETH.MESH.03801571, were marked for identification.)

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BY MR. SLATER:

Q. Dr. Arnaud, I've given you an e-mail chain from September 2002 that we've marked as Exhibit 1254.

Did you have a chance to look at that during the break?

A. I had.

Q. This e-mail chain talks about the regulatory background to getting product into the hands of the doctors who you wanted to do clinical study on the TVM technique. Correct?

MS. KABBASH: Objection.

THE WITNESS: Yes.

BY MR. SLATER:

Q. Now, I understand you didn't work in

the regulatory department, but did you have an understanding of what the considerations or concerns were as described in this e-mail chain in September 2002 about getting Gynemesh® into the hands of the doctors who were going to do some clinical study on the TVM technique?

A. Well, to be honest, I'm not very familiar with all this chain of e-mail. I know I was on copy, but as you mentioned, I'm not very familiar with the regulatory aspects, because, of course, in our company, there are people who are much more qualified than myself.

Q. The material that was being used in the TVM technique and that ultimately was used in the Prolift® was Gynemesh® PS. Correct?

A. Yes, yes.

Q. At this time, in September of 2002, was Gynemesh® PS cleared through the European regulatory authorities for the use for pelvic floor repair?

MS. KABBASH: Objection.

THE WITNESS: I don't know. I cannot remember, you know. It's too long time ago and not something I was really involved with.

BY MR. SLATER:

Q. If you could look on the second page of the e-mail, it indicates, there's an e-mail from someone named Manuel Vera Arcetti. And he wrote to yourself and a few other people on September 18, 2002. And he addresses you. He says, "Axel, can you approach Martin Weisberg and talk with him from the clinical standpoint? Can you write the Expert report yourself and co-sign with somebody from the" clinical/medical affairs "team?"

Do you see that?

A. Yes, yes.

Q. And did you have an understanding of why you were being asked to write a clinical expert report for the proposed trial with this TVM technique?

A. I don't. I'm sorry, I don't.

Q. Just below that in the next paragraph there's a sentence that says, "We MUST have the PS" -- that would be Gynemesh® PS. Correct? Prolene® Soft?

A. Where --

Q. The next paragraph, under where it says "Axel"? It says, "Greg is getting back to us at the end of this week with an answer on the recommended approach," and "we need to make sure

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that they understand the timing implications of this. We MUST," in all capital letters, "MUST have the PS material by early October for the TVM team."

Do you see that?

A. Yes, I do.

Q. Now, the reference to PS would be Prolene® Soft Mesh. Correct?

A. Yes. I guess, yes.

Q. And Prolene® Soft Mesh was a hernia mesh, a mesh that was developed for hernia, and then ultimately, when that mesh was going to be used for pelvic floor, the company named it Gynemesh® PS. Correct?

MS. KABBASH: Objection.

THE WITNESS: It's my broad understanding. I don't know the detail, you know. Sometimes the product might be essentially the same but differ by some characteristic, some minor characteristics. Or I cannot, you know, tell you with 100 percent certainty the two products are the same, but I guess they are very similar at least, because Gynemesh® called Gynemesh® PS, so PS means Prolift® Soft.

BY MR. SLATER:

Q. Why was it at that point in time in

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September of 2002 was it so important to have the material, the mesh material, to the TVM team by early October? Why was that timing so strict?

A. Well, I have no idea. You know, I suspect, but it's only speculation, that it was for a matter of respecting the delay of the project.

Q. Do you remember? Obviously you were involved and you were addressed in that e-mail. Was one of the considerations to try to make sure you moved along quickly?

MS. KABBASH: Objection.

THE WITNESS: I don't know honestly. This is not really the area I was very much involved. You know, I was essentially taking care of the medical aspect. Everything else linked to regulatory affairs, well, I had enough work to do without, you know, taking care of that.

BY MR. SLATER:

Q. Well, one of the things you had to do, though, in your position was to interact with people in various departments. You had to interact with the marketing people. You had to interact with the regulatory people. That was part of what you did. Right?

A. Yes, yes.

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Q. And you understood that you had to have -- well, rephrase.

You had to understand what their considerations were so that you would all be aligned on moving the project forward efficiently. Right?

A. Yes.

MS. KABBASH: Objection.

BY MR. SLATER:

Q. And if you go to the next e-mail, which is actually on the first page, because it goes in reverse order, there's an e-mail in the middle of the page from Marie-Jose Plique dated September 19, 2002. And she addresses yourself and some others and says, "The first option is definitively the best."

And she's talking about there were two options described here as to how to get the material cleared or be able to be allowed to use the material for the European Union clinical trial for the TVM technique. Correct?

MS. KABBASH: Objection.

THE WITNESS: I don't know.

BY MR. SLATER:

Q. Well, she says, "I am concerned by delay regarding labelling and IFU translation." Do

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you see that? Do you see that sentence? It's the first sentence of her e-mail.

A. Oh, yeah, yeah. "I am concerned by delay" -- okay.

Q. Again, does this refresh your recollection as to why there was concern about delay and why things needed to move quickly?

MS. KABBASH: Objection.

THE WITNESS: Not really.

BY MR. SLATER:

Q. In the next e-mail at the top of the page, again, Manuel Vera Arcetti --

And who was that person, do you remember?

A. It was a marketing person.

Q. Generally on a product -- well, rephrase.

And on this product, the marketing people would have a great deal of input into bringing the product -- the project along. Correct?

A. Well, of course, when we were developing a project, there were different kind of people, and there was always a person representing marketing in the project team. So Manuel Vera Arcetti was the marketing person in charge of being

in the team, you know.
Q. And in Manuel's e-mail, September 19, 2002, he says, again, at the very end of that e-mail, "We need to ensure that some PS material is available for Axel & Jacquetin by early October."
Do you see that?
A. Yes.
Q. So it was clearly a priority to make sure that the material, the mesh material, would get to Prof. Jacquetin and the group to start clinical trial with the TVM technique by October. There was a push to get that done. Right?
MS. KABBASH: Objection.
THE WITNESS: It's possible, but I don't remember.
BY MR. SLATER:
Q. Well, that's what the e-mail says certainly. Correct?
A. Yes, that's correct.
Q. I'm now going to hand you what I've marked as Exhibit 1255. And we're going to fast forward a little now from September 2002 to this document, which is the meeting minutes of the kickoff meeting that took place April 14, 2003 for what the project was now referred to as anterior

TVM, it gets the name Porthos, chartering concept - feasibility.
Do you see that?
A. Yes.
Q. And that's just part of the way that things work within Gynecare and Ethicon, that when a project is going forward, it gets a code name basically, and it goes by that name until the end, and then ultimately a marketing name would be assigned to the product if it goes to market. Correct?
A. Yes, that's correct.
Q. Let's look at the team members that we have on this document, a few of them.
You have US marketing, Paul Parisi is part of the team. Right?
A. Right.
Q. From clinical, we have Cyrus Guidry. Correct?
A. Yes.
Q. From regulatory, we have Sean O'Bryan. Correct?
A. Correct.
Q. From research and development, it says Axel Arnaud. Right?

A. Yes.
Q. Again, at this point, you're the scientific director of Gynecare. Correct?
A. Yes.
Q. Also from research and development we have Scott Ciarrocca. Correct?
A. Correct.
Q. And also from research and development we have Gene Kammerer. Correct?
A. Yes.
Q. And if you turn to the next page, the minutes, first there's a "Briefing" listed under the "Agenda." And then there's a section, "Discussion highlights." And the first discussion highlight from that April 14, 2003 meeting says, "Kit content" and "concept."
Do you see that?
A. Yes.
Q. And at this meeting, it was discussed, "Current anterior TVM kit layout as used by Groupe TVM may not justify premium price. Challenge to" research and development "to come up with concepts that add more value and fit strategically with posterior TVM," which was then code named Aramis, and something else called

Mulberry.
Do you see that?
A. Yes, I do.
Q. And you had an understanding as of that time that the marketing people wanted research and development to come up with concepts with this TVM system, which was ultimately the Prolift®, that would allow them to charge more money for it. Correct?
MS. KABBASH: Objection.
BY MR. SLATER:
Q. That's what they're saying when they say to justify a premium price. Correct?
A. Give me one second.
Well, I can't speculate -- if I remember correctly, of course, in the TVM, in the Prolift®, you have two part. One is the mesh and the other one is the other tools. So I believe at that time the only product was fixed was the design of the mesh. But in our experience, have been involved in many project, you know, to offer a precut mesh, this is not a very good business for a company, because, you know, a precut mesh, it can be copied in different countries. You know, in country with a low level of resources, people will just take

a pair of scissors and cut a regular piece of mesh.

So I think what he means was, well, this project is going to cost a lot of money, so on the other hand, we need to provide at the end of the day something that is profitable. If it's just -- the matter is just to provide a precut mesh, this is not something that's very attractive as a company.

So that's my understanding of this first line. So not just a precut, but we need to provide more -- you know, we need to provide tools that makes it a little bit more attractive, you know, and easy to handle. But that's my interpretation for what they say.

Q. And at this time, in April of 2003, Gynemesh® PS, which was sold as just a rectangular shape of mesh, that was being made available on the market to pelvic floor surgeons to cut and shape as they wanted to, to use as they saw fit. Correct? That was on the market offered by your company. Right?

A. Yes, absolutely correct. But with the Gynemesh® PS as it existed, the size was too small to get, you know, the same product that we were thinking about.

Q. And certainly you understood and the

team understood at that time that you were anticipating charging significantly more money for the Prolift® kit than what you were charging for Gynemesh®. Correct?

MS. KABBASH: Objection.

THE WITNESS: Well, of course Gynemesh®, what was Gynemesh®? Gynemesh® was a textile, piece of textile, sold on the market to be used in the pelvic floor. But no technique was associated to this. It was something for the surgeon. If you wish to use a piece of mesh, you have Gynemesh®. So Gynemesh® was not a very sophisticated product. It was just, you know, an adjunct for the repair.

What we had in mind was to develop a full procedure, a full solution, so something which is much more attractive. Because the issue with Gynemesh® was that there was no technique described to use it, so it was for individual surgeon who had -- who felt the need to use a textile with their own technique. Well, what was our purpose with Prolift® was completely different. It was not just to just provide a piece of textile to the surgeon. It was -- our goal was to provide an alternative to a colporrhaphies that can be reproduced all over the

world, that can be told in textbook, can be explained in prof ed, you know.

So we are not talking at all about the same thing. You know, the objective was a little bit more ambitious, you know, to provide clinical trial, to really change the rule of the game in this surgery.

BY MR. SLATER:

Q. So if somebody were to suggest to you that the Prolift® was not significantly different in any way from the Gynemesh®, you would strongly disagree with that?

MS. KABBASH: Objection.

THE WITNESS: Well, it depends what you mean by Prolift®, because Prolift® is both a procedure and a product, so...

BY MR. SLATER:

Q. I'll answer your question, make it clearer.

If somebody were to say the Prolift®, the entire system, including the procedure, the mesh and the instruments as it was sold, as compared to Gynemesh® as it was sold, if someone were to say the Prolift® did not have any significant differences from Gynemesh®, you would disagree with that

statement?

MS. KABBASH: Objection.

THE WITNESS: Well, there are aspects that are similar. The material is the same, so the tolerance is likely to be the same. Now, the size is completely different. The aim of the Prolift® was to create a barrier to all the potential defects in the pelvic floor, a whole barrier. So that was not all the case with the Gynemesh®. So in some way, the mesh is the same, but the technique is completely different.

BY MR. SLATER:

Q. Let's go to the second part of the "Discussion highlights," "Clinical trials."

Do you see that, back in the document here, in the middle of the second page?

A. Yes, yes.

Q. It says, "Groupe TVM," that's Prof. Jacquetin and the French surgeons and European surgeons you were working with. Correct?

A. Yes. You can say French surgeon, because they were all --

Q. They were all French?

A. -- they were only French.

Q. It says, "Groupe TVM (+ 3 US

surgeons) will conduct clinician sponsored clinical trial on the procedure."

And that's referring to the TVM procedure. Correct?

A. Yes, yes.

Q. And at that point, it was projected that this would occur in September 2003 with a three-month follow-up. Correct? That's what it states in the minutes?

A. Yes.

Q. And then it says, per the discussion, "From a marketing point of view," and then it says, Paul and Celine, which that's Paul Parisi and Celine Buard, they were the two marketing people at the meeting, "this will be sufficient data to launch the product."

Do you see that?

A. Yes.

Q. So the marketing people weighed in at this meeting and said, look, in order for us to market this product, we just need three-month data on the TVM procedure. Correct?

MS. KABBASH: Objection.

THE WITNESS: Yes. That's what I read.

BY MR. SLATER:

Q. And then it says, "Accordingly, additional clinical trials will not be part of the project plan, nor in the budget."

That's what was discussed at the meeting. Correct?

MS. KABBASH: Objection.

THE WITNESS: That's what I read, yes.

BY MR. SLATER:

Q. That's what the minutes reflect. Right?

A. Yes.

Q. And then if you go to the next page, it says, "Pipeline Committee's approval: May 2nd."

And that's one of the things that a project has to do when it goes through Gynecare or Ethicon, it has to go through different committees. And one of the committees would be the pipeline committee. Correct?

A. Yes.

Q. That was anticipated to be May 2nd, according to this, May 2, 2003. Correct?

A. Yes.

Q. And then it says, "Stage Gate

Review," which would be another step the project would have to go through for approval, was anticipated to take place on June 27, 2003. Correct?

A. Yes. Absolutely, yes.

But just to comment, you know, this is the first meeting. So marketing people make suggestion, but then there is a process of approval of the project that might change the scope completely. So the opinion of Paul Parisi and Celine Buard were preliminary opinion, you know, before it goes through a long stagegate process. So that's what I wanted to say.

Q. What we do learn from that part of the document, though, is that the marketing people weigh in heavily from their perspective of what type of clinical data they thought they would need in order to be able to successfully market the product. Correct?

MS. KABBASH: Objection.

THE WITNESS: No. I --

BY MR. SLATER:

Q. That's part of the process?

MS. KABBASH: Objection.

THE WITNESS: No, I won't agree with

that. I don't think the marketing people have had any influence in this. You know, I think this is essentially a medically-driven project. And I don't remember any influence marketing could have in this project.

MR. SLATER: Let's just go off for a moment.

THE VIDEOGRAPHER: The time is now 12:11. We are going off the record.

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(Deposition Exhibit No. Plaintiff's-1256, E-mail dated 18 Jun 2003, Bates stamped ETH.MESH.03803483; Deposition Exhibit No. Plaintiff's-1257, PowerPoint, "ATHOS/ARAMIS/PORTHOS, Concept -> Feasibility, June 27, 2003," 33 pages, and Deposition Exhibit No. Plaintiff's-1258, PowerPoint, "ATHOS/ARAMIS/PORTHOS, Concept -> Feasibility, June 27, 2003," 46 pages, were marked for identification.)

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MS. KABBASH: 1257 is a draft?

MR. SLATER: 1258, based on what you guy produced, is the final.

MS. KABBASH: So the 1257 says June 27 on it.
MR. SLATER: They both say that, because that's the day of the meeting.
MS. KABBASH: Oh, I see.
MR. SLATER: Got it?
So 1257 is the one that was attached to the June 18 e-mail. The metadata shows 1258 to be the last version that existed before the meeting. This is June 25th.
MS. KABBASH: Okay.
MR. SLATER: I mean, I have no problem with telling you that.
MS. KABBASH: Okay.
MR. SLATER: And I have the metadata here. And there was nothing else produced, so this would have to be the final. If it's not, you guys have it somewhere in a shoebox.
- - -
(A discussion off the record occurred.)
- - -
THE VIDEOGRAPHER: The time is now 12:18. We are back on the record.
BY MR. SLATER:

Q. I've handed you three exhibits. Exhibit 1256 is an e-mail dated June 18, 2003. And it was written by Scott Ciarrocca to a whole group of people, and one of them is yourself. Right?
A. Correct.
Q. And it's regarding the stagegate presentation that we were just talking about, that meeting that was scheduled now for June 27, 2003, to keep the project moving forward through the steps that the company requires at the different steps of the project. Right?
A. Right.
MS. KABBASH: Objection.
BY MR. SLATER:
Q. And the e-mail from Scott Ciarrocca says, "All...please find a draft presentation for the combined Athos/Porthos Stagegate on June 27." And we have on the screen the PowerPoint presentation that he's referring to. We have the front page.
Do you see that?
A. Yes.
Q. Just very briefly, what did Athos stand for and what did Porthos stand for, if you remember?

A. I do.
Q. Please tell us.
A. I don't know in English, but, you know, it's The Three Musketeers. It's the name of the --
MS. KABBASH: The Three Musketeers? That's what we call them, too.
THE WITNESS: In English it works? Three Musketeers from French author.
BY MR. SLATER:
Q. And the name Athos was given to what part of the TVM?
A. I think I remember, because I fight with the company, I said Athos should be anterior, but I guess Athos was posterior. And Porthos was anterior, if I remember correctly. And I did not find that very good.
Q. Well, do this. Turn to page 4. And let's go to page 4 of the PowerPoint. I just turned to the page and saw that we actually have it listed.
So according to this, the original pelvic -- the "Project Evolution" is described.
Do you see that?
A. Yes.
Q. And it says, "Original" pelvic floor

repair "Projects Approved For Concept Efforts in November 2002." And at that point, it was listed as three, Athos, which was for vault suspension or apical defect repair.
That would be the top of the vagina. Correct?
A. Yes.
Q. Aramis for the posterior defect, which would be if there was a rectocele. Correct?
A. Yes.
Q. And Porthos or Porthos, anterior defect, that would be for a cystocele, the bladder dropping down. Correct?
A. Yes, yes.
Q. If we forward turn now to the "Unified Project Objective," page 7.
And what this states is, the unified project objective at this stagegate meeting was to be -- "To Develop A Proprietary Set Of Procedures And Tools For Performing Standardized Mesh Repair Of Pelvic Floor Defects That Satisfies The Identified Unmet Needs."
That was the definition of what the objective was. Correct?
A. Correct.

Q. It then says, in the first bullet point under that, "510(k) Regulatory Approval And CE Mark."

Do you see that?

A. Yes.

Q. And the second bullet point says, "Provide Data From A Multi-Site" European Union/United States "Physician-Sponsored Clinical Trial To Support The Launch."

That was the second thing that was expected to be done. Correct?

MS. KABBASH: Objection.

THE WITNESS: Yes.

BY MR. SLATER:

Q. The third thing, "Complete All Development Work By" third quarter 2004.

That's what it says. Right?

A. Yes.

Q. So these were some projected things that needed to be done over the course of time with this project?

MS. KABBASH: Objection.

THE WITNESS: Well, it seems to be.

BY MR. SLATER:

Q. Okay.

Now, just to stay sequential through this PowerPoint, could you turn to the next page? And it's Page 8, and it actually has an anatomical illustration of the TVM procedure, the total procedure. And if you would, just if you need to confirm it, Exhibit 1258 is the final, according to what's been produced to us, the final version of this presentation that was actually submitted or presented at that stagegate meeting June 27, 2003.

And on page 8 of both of these, there's actually a picture that depicts the total procedure. Correct?

A. Yes, yes. Seems correct, yes.

Q. And does this accurately represent what would be done in the total TVM, ultimately named the total Prolift®? Is this illustration accurate? I'm not saying it covers every small detail, but is it a fair representation of what the procedure ultimately does?

A. To my best knowledge, it is. You know, I'm not saying that the -- it is the final design of the product, but at that time, that was the -- I know very well this drawing, because I ask an artist to do them. But, you know, I know that this is early stage. Probably the final product was

maybe different from what is there. It was different. But the basic principle of what we tried to achieve are in this, I believe.

Q. When you look at these diagrams of the total procedure based on the fact that you actually commissioned these illustrations and you know what the final Prolift® procedure was, are there any significant differences between what is depicted here and what one would depict for the total Prolift® procedure at this level?

A. I need some time, because very technical.

Well, the global idea is there, you know, so... That's all I can say, you know, the global idea of the Prolift® is in this drawing.

Q. Fair enough. And that's what I was asking.

If you then turn to page 10?

MS. KABBASH: Are you back on the draft now, Adam, or on --

MR. SLATER: Yes.

BY MR. SLATER:

Q. On page 10 again, do we see a similarly fair representation of the posterior TVM procedure, as it ultimately was -- and as it was

ultimately marketed as the Prolift®?

MS. KABBASH: Objection.

THE WITNESS: I think on this slide, we see two variation, potential variation, you know. In the middle, the fixation is done by straps passed in the sacrospinous ligament. In the right-sided drawing, there seems to be a direct fixation by a mechanical mean to the sacrospinous ligament. So it's two potential variation of the same -- for achieving the same goal.

BY MR. SLATER:

Q. At that time, the thought was to use a fastener device to actually fasten the strap to the sacrospinous ligament. That was the plan at that time. Correct?

MS. KABBASH: Objection.

THE WITNESS: No. You know, that's very important point for, you know, the TVM Group. And if I can try to explain you. They did not want to have a mechanical attachment, because in Jacquetin experience, Jacquetin was used to put the mesh that was attached by suture to the two arcus tendineus. And when the tissue postoperatively shrink, you know, it pulls on the fixation and can lead to pain.

So that's why the TVM Group wanted and preferred to have an attachment that was going to be done by passing an arm through the ligament and rely on the friction of the arm; because they believed that this would be a more, let's say, flexible and adaptive way, if -- when the tissue start to contract in the wound healing phase. So there was -- this was a key point for us that we should have no direct fixation to the ligament but rather, you know, strap that goes through it and a certain amount of adaptation in the postoperative phase.

BY MR. SLATER:

Q. Why was it that this stagegate presentation, and many of the discussions I've seen in the documents describe attempting to use a fastener to attach the strap to the sacrospinous ligament? Was that an idea that came from within Gynecare and Ethicon but something that was different from how Prof. Jacquetin was doing the procedure?

A. Well, I don't know exactly, but, you know, basically all the means have been thought about and maybe an alternative could be to have a fastener with a shortly absorbable product, for

example, so --

Q. Well, if you look at the next page, you see the fastener gun. I mean, this was a prototype that your company was trying to develop. And the thought, at that point, was to use a fastener and to attach the strap to the sacrospinous ligament. Ultimately that idea was dropped, but that was the thought at that time. Right?

MS. KABBASH: Objection.

THE WITNESS: Yeah. You know, at that time, we were in the -- really in the phase where everything was open for.

BY MR. SLATER:

Q. Well, you're about to hopefully, from your perspective, based on the documents we've seen, you're hoping to go to clinical trials within a few months. Right?

A. Yes.

Q. And let me understand this.

When Prof. Jacquetin developed the TVM technique with his group, was there a fastener that would fasten the strap to the sacrospinous ligament or was he passing it through the ligament?

A. Passing it through the ligament.

Q. Whose idea was it to try to use a

fastener device to fasten the strap to the ligament? Where did that idea come from?

A. I don't know. But, of course, it's the most obvious idea. If you want to affix something, you use a fastener. But I'm sure that maybe the engineer in Somerville made this fastener. When they presented that to the group, I don't remember specifically, but I'm sure the group was strongly preferring, you know, the mesh going through the ligament.

Q. Do you know why the fastener device and the fastener system was not used with the Prolift®? Do you know why that idea was dropped? You ran the project, so I'm asking you.

A. No, no. I understand. I believe, you know, the engineer used to come to France with a lot of device of possible solution, and probably this one was one of them. But I'm sure the TVM Group would have rejected this, because they didn't want to have a fixed attachment.

Q. Well, the TVM Group certainly knew that your company was proceeding with this project with the fastener device and the fastener system included. They must have known that your company was proceeding with that assumption. Right?

MS. KABBASH: Objection.

THE WITNESS: Yeah, but, you know, I think what you see there is not a functional device. It's just, you know, this kind of device they can make in a couple of minutes with a machine and come back in France and show this to the doctor, say, what would you -- would you like to have such a system. And the doctor might say, no, we don't want. We want something that go through the ligament.

BY MR. SLATER:

Q. So during the development of this project, at the point that the June 27, 2003 stagegate meeting took place, the idea of fastening the posterior straps to the sacrospinous ligament was under consideration. Correct?

A. I don't know. I was not in the meeting.

Q. It's in the PowerPoint that was presented. Right?

A. Yeah, yeah. It was presented as a potential solution, I think, but...

Q. And ultimately that idea was dropped. Right?

A. I don't -- it was dropped for sure,

because this was not in the final product. For what reason -- you know, I know the reason. The reason was that the group was very attached to the idea of something being mobile through the ligament instead of something being strongly fixed in the ligament to avoid, you know, pain.

Q. And the group and yourself and the others within the company were very cognizant and aware that if the straps that would be used to help to secure what would ultimately be the Prolift® device, if they would get tight and there would be pulling on them, that that could cause pain to patients. Correct?

A. Yes, yes. That was well known from the experience of Jacquetin. So that's why we didn't want to replicate the same mistake of a tight fixation to the ligament.

Q. So it was very important to make sure that any surgeon who would ultimately use the Prolift® would know that if tension or tightness of the straps occurred, that that could cause pain to patients. Right?

A. Absolutely. This was quite obvious for surgeon.

Q. Well, it was certainly --

It was certainly obvious to yourself and the TVM Group. Correct?

MS. KABBASH: Objection.

THE WITNESS: Yes, yes.

BY MR. SLATER:

Q. Let's go to page 13, which is the "TVM Procedure: Anterior."

And, again, is this a representation of what the procedure was thought to be at that time?

A. Yes, yes, it is.

Q. Are there any significant differences between what is illustrated here and what ultimately was marketed as the Prolift® procedure?

MS. KABBASH: Objection.

THE WITNESS: But to my best knowledge, I don't see major, you know, the principle on there.

BY MR. SLATER:

Q. If you could, turn to page 20. On page 20 is a list of resources and manpower.

This just lists the people who are working on this project. Correct?

A. Absolutely, yes.

Q. Now, you're not listed on there, but

obviously you were at the head of this project, along with Ophelie Berthier had a very important role as well. Correct?

MS. KABBASH: Objection.

MR. SLATER: Well, let me rephrase the question.

BY MR. SLATER:

Q. You're not listed on this list, but obviously, you had significant involvement. Right?

A. Yes, yes. I'm a little bit upset to see this, because I'm wondering why I didn't appear there. But that was in June 2003, and -- well, clearly, I was still in the project, you know.

Q. Some of the people listed here include medical affairs, Marty Weisberg. From corporate product characterization, which says CPC, you have Elizabeth Vailhe. From PL, you have Scott Ciarrocca. From Gynecare R&D, you have Gene Kammerer. And from regulatory affairs, you have Sean O'Bryan.

That's some of the people listed here. Right?

A. Yes, yes.

Q. And if you could turn to the next page, there's a timeline. And it matches up with

the final version on page 32. If you need to compare them, I believe there are a few differences in the dates. So let's look at page 32 of the final version, which is 1258.

The timeline is listed there. There are some "Milestones."

Do you see that?

A. Yes, yes.

Q. And the milestones as projected in June of 2003 were to get the clinical study initiated and started by September 2003. Correct?

A. Yes.

Q. And to get the 510(k) submission for what would ultimately be the Prolift® filed by January 2004.

That's what's listed on this document. Correct?

MS. KABBASH: Objection.

THE WITNESS: Can you repeat that?

BY MR. SLATER:

Q. Sure.

On this document, this stagegate presentation that was made, one of the milestones that's listed is 510(k) submission, and that's dated as January 2004. Right?

A. Yes.
Q. And the next entry says, "510(k) Approval," May 2004. Correct?
A. Yes.
Q. And, again, this is for the project that ultimately was the Prolift®. Correct?
MS. KABBASH: Objection.
BY MR. SLATER:
Q. That's what this presentation is. Right?
A. Yeah, I think so.
Q. And that they were anticipating at that point a product launch in September 2004.
That was the milestone that was set at that time. Correct?
A. Well, that's what's on this document.
Q. Go to page 23, if you could. It's titled "Critical Assumptions: Project."
MS. KABBASH: In the final?
MR. SLATER: It's page 34 in the final, which is fine, you can look at that, because I'm only going to point to a couple.
BY MR. SLATER:
Q. So let's look at the final version of this presentation that was submitted. And we'll

just put the final version up on the board now.
The first critical assumption for this project, the first bullet point says, "US Regulatory Pathway Is 510(k)."
That's what's listed here. Correct?
A. Correct.
Q. Two further down, two bullet points down, it says, "Clinical Trial Of Implants With 6 Month Follow-Up Will Be Sufficient To Support Launch."
That's another critical assumption. Right?
A. Yes.
Q. It says "Clinical" -- rephrase.
The clinical assumptions for the project, the fourth bullet point indicates, "Clinical Trial Will Not Be Required For Fasteners Or Ancillary Components."
Do you see that?
A. Yes.
Q. So at that point, it was anticipated that the fasteners would be part of this system. Correct?
MS. KABBASH: Objection.
BY MR. SLATER:

Q. That's why it's listed there. Right?
A. Yes. It may be, you know. Maybe. But the fastener or the ancillary component. So it does not mean that at this time we had decided there should be a fastener.
Q. The ancillary components are the instruments. Correct?
A. Yes.
Q. The fifth bullet point under the critical assumptions for this project says, "No Major Competitive Offerings With Similar Features" or "Advantages Enter The Market Ahead Of Us."
Do you see that?
A. Yes, yes.
Q. And do you recall that that was very important to Gynecare and Ethicon, that this project would get to the market first? That was one of the things you wanted to accomplish?
A. Well, to be honest, we had absolutely no doubt that we were the only one working in this area.
Q. You thought you were the only one?
A. Absolutely.
Q. Do you recall the AMS Apogee® and Perigee®?

A. Yes.
Q. Do you recall that they got to the market actually before the Prolift® did?
A. Yes.
Q. And when did you first learn of the existence of the Apogee® and Perigee® projects?
A. When they entered the market.
Q. Your company didn't know in advance that AMS was working on the Apogee® and Perigee®?
MS. KABBASH: Objection.
THE WITNESS: Not at all.
BY MR. SLATER:
Q. If someone in Ethicon or Gynecare knew that the Apogee® and Perigee® projects were underway and those products were going to be going to the market soon, nobody informed you is what you're telling me?
A. No. It was a surprise, you know, to see that the work we have been conducting for more than five years suddenly arrived on the market. And I know how it worked, but I keep it for myself.
Q. When you say you know how it worked, what do you mean by that?
A. At some point, there has been some -- you know, how can I say that in English? Some, you

know, the confidentiality of what we were doing was broken. And this is probably the very likely reason why this went in this way.

MS. KABBASH: Dr. Arnaud, I want to remind you in your testimony that you are not supposed to guess on anything that Mr. Slater asks you. So obviously if you know facts, you testify about them. But nobody wants you to guess.

THE WITNESS: Yeah. You know, I'll tell you. Prof. Jacquetin was so excited to come on the market -- no, not to come on the market, to show his procedure to the surgical community, at some point he made presentation of these pictures. And he thought, very naively, that because a patent has been filed, he could do it. So as early as 2003, he showed that in some meetings. So, of course, that was not a very good idea. And that's probably why the things went in that way.

BY MR. SLATER:

Q. That's your understanding?

A. My understanding, yes.

Q. Did you ever discuss this with Prof. Jacquetin?

A. Yes.

Q. And did he acknowledge to you that

that had occurred?

A. Yes.

Q. Did you ever pin down who it was that watched that presentation and brought the information to AMS?

A. Well, you know, it was public -- public presentation, so...

Q. So whoever attended could have had -- could have shared that information with AMS?

A. Yes, yes.

Q. Did you know before the AMS product got on the market that Prof. Jacquetin had shared that information in a public meeting?

A. Yes, yes. He had shared some information, some drawing, you know. And he not say, well, I'm working with Ethicon on that, but the drawing were quite self-explanatory. You know, the drawing he showed me have been shared before the product launch in some medical event.

Q. Did you know that that had occurred and that AMS was aware of your project before the AMS products came to the market?

A. I don't know.

Q. You don't remember?

A. I don't know if AMS was aware of what

we were doing, but it was not a big secret what we were doing, but we thought we were such in advance, you know, because we were working for five years -- for three, four years on that that no one could come on the market before us.

So this assumption that is there, you know, is something I see in every single presentation of a project. When you look at the risk of the project, it's a general topic. If someone come on the market before us, it's going to lead us to reconsider all the plan. You know, it's a general item that is in all the projects that is not going to be very good for us if someone come on the market before us.

Q. When the AMS products came on the market, the Apogee® and Perigee®, you said you were surprised?

A. We were in some way, yes.

Q. Were you concerned now that AMS had gotten to the market with a kit comprised of mesh to repair prolapse before you had gotten to the market? Was that a concern?

MS. KABBASH: By the way, when you say "you," you're talking about him personally. Right?

MR. SLATER: Right. Well, I'll ask the question clean.

BY MR. SLATER:

Q. At the time the AMS products came to market, were you, and to your knowledge other people within the company, now concerned because AMS had gotten to the market first with a kit for the treatment of prolapse?

A. Well, first of all, we were disappointed in some way, but on the other hand, you know, their device seemed to us to be so far away from where we were, we have been designing, so let's say, simple, or what can I say, so unattractive to us that we -- in some way, we were a little bit upset they were before us, but on the other way, a little bit reassured that they have a device that would probably be much less attractive for surgeon done the one that was in the development phase.

Q. Were there significant differences between the AMS Apogee® and Perigee® and the Prolift® systems?

MS. KABBASH: Objection.

BY MR. SLATER:

Q. From your perspective, were there significant differences?

A. Well, as I can remember, the most significant difference was in the tools. You know, our tools were much more advanced, to my best recall, you know. We had been working on the tools, which was the major challenge, one of the major challenge for R&D, the tools. And the AMS tools were not that innovative. And also we were confident our mesh was a very good mesh. And I'm not saying superior, but an excellent product.

Q. Did you feel that the Prolift® procedure for implanting the mesh had significant differences from your perspective as compared to the procedure --

A. Sorry.

Q. Sorry. I will reask the question.

A. Excuse me.

Q. No problem.

When you looked at the AMS product, did it come with a procedure as well, a procedure to place that mesh, like the Prolift® which had a procedure dedicated to the Prolift®?

A. I think so, yes. It was something very similar.

Q. Were there any differences that you thought were significant between the methods by

which the Apogee® and Perigee® would be put in the body versus the Prolift®?

MS. KABBASH: Objection.

THE WITNESS: That's a long, long time. But, you know, what I remember is that we were confident our product would be much better on the market for three -- for a couple of reason. First of all, tools are more advanced. It seems to us that what AMS was putting on the market was what our project was one year ago, you know, so more advanced tools for us, better mesh and also clinical data that were ongoing. So we were upset, but we were quite confident that this would not be a major competitor.

BY MR. SLATER:

Q. When you compare the AMS products, the Apogee® and Perigee®, versus the Prolift®, the size of the mesh was different. Correct?

A. I think so.

Q. And the tools were very different. Correct?

MS. KABBASH: Objection.

THE WITNESS: Well --

BY MR. SLATER:

Q. I'll ask it differently. She

objected, so I'm going to ask.

Were the tools very different as between the Prolift® and the AMS products on the other hand, the Apogee® and Perigee®?

A. Well, to my best remembering, because there have been so many of these products, you know, the Bard product, the Boston product, our product were innovative, you know, with this cannula, and their product has nothing -- their tools add, to my best knowledge, nothing really exciting. This was very -- very simple tools to put the mesh in place. And we have an advanced tool to make the life of the surgeon easier and the risk of the procedure lower. So we were working in a way to help the surgeon to put the mesh in place with reproducibility and safety.

Q. So when you compare the tools between the Prolift® and what went on the market with the Apogee® and Perigee®, from your perspective, the tools were very different. You felt the AMS tools were much simpler, as compared to the tools with the Prolift® that you felt were much more advanced.

MS. KABBASH: Objection.

BY MR. SLATER:

Q. Is that a fair summary?

A. Well, their tool were basic tool that did not provide any -- much additional value for the surgeon. Our tools have been such more extensively and were providing easiness to put the mesh in.

Q. What was the specific difference in the tools, if you can recall?

A. Yes, I can recall.

You know, what is difficult when you are performing this operation is to pass something in a way and then go back in the other way. So all the challenge was, well, if you have a needle, if you go that way, it's fine, it's easy, but now if you want to go back, you cannot go back easily. So all the change of our engineer was, well, once I've done that, how could I take this 180 percent return way, you know. So that was the challenge. That's why the cannula was there and this very clever system was developed.

And to my best knowledge, that was not the case in the AMS system. You know, the AMS system had no solution for going one way and getting back the other way.

Q. When the AMS Apogee® and Perigee® came to the market, did the team that was developing the Prolift® feel at that point that you needed to

move quickly to get to the market as quickly as possible?

A. Well, I would say no, because, you know, in a big company, to move quicker is extremely difficult, you know. To accelerate -- in a small company, you probably can accelerate. In this case, well, they are on the market, fine. It's a matter of a couple of months or what. We were confident that they were on the market, fine, but what we were going to introduce on the market would be so much better and so much more attractive for the surgeon, it wasn't a big issue to have them on the market. It's a disappointment but not an issue.

Q. In order to get the Prolift® to the market quicker once the AMS products were now on the market, was the decision made not to follow the US regulatory pathway of getting the 510(k)?

MS. KABBASH: Objection.

THE WITNESS: No, no, no. That -- no.

BY MR. SLATER:

Q. Were you involved in the decision not to seek 510(k) clearance in the US for the Prolift®?

A. No, I was not at all involved in this kind of decision, because as you see, I'm not even

in the team, so it's really a US issue.

Q. Were you told at any time before the Prolift® was launched that Gynecare was not going to seek 510(k) clearance for the Prolift®? Were you aware of that?

A. Absolutely not.

Q. When did you first learn that the Prolift® was initially marketed in the United States without 510(k) clearance?

MS. KABBASH: Objection.

THE WITNESS: Well, I learned something like that recently looking at, you know, on the web, maybe last year. So very recently.

BY MR. SLATER:

Q. If you could turn to the next page of the final presentation, page 35. Again, this is the stagegate presentation of June 27, 2003 for the project that ultimately was the Prolift®. I just want to ask a couple more questions about these critical assumptions regarding the product.

It says in the fourth bullet point, there was an assumption that was described as critical "Creates No Additional Problems Possible With Needle Passage Through Obturator Foramen," and then in parentheses, "Bladder, Vessel, Nerve,

Urethral Perforation."

Do you see that?

A. Yes.

Q. And what is that telling us? What was that assumption?

A. Sorry, I don't understand.

Q. What does that mean? Basically I'm asking you, what does that mean?

A. Okay. We were assuming that the product we were going to develop would not create additional problem with the needle -- okay.

You know, passage through the obturator foramen is something that was not new, because it was used by the people for the sling surgery, incontinence surgery. So going through the obturator foramen was something well known, but we did not want to add additional risk, because instead of one passage, there will be two passage. So if two passage was a -- we knew that one passage was safe, but we could not accept a second passage could be dangerous. That's basically what it means.

Q. The fifth bullet point on the critical product assumptions says, "Creates No Additional Complications," and then it says, "Erosion" and "pain."

What does that mean?

MS. KABBASH: Objection.

THE WITNESS: So we are assuming the product would not create additional complications. Additional to what, I don't know, because I was not in this meeting. But I guess it is -- I make a guess. We knew --

MS. KABBASH: I don't want you to guess. If you're going to guess, I don't want you to answer the question.

MR. SLATER: You shouldn't cut him off in the middle of an answer.

MS. KABBASH: If it's a guess, I absolutely should. If he's saying --

MR. SLATER: No, you actually shouldn't. You really shouldn't stop your witness in the middle of an answer, because he may -- you don't know what he's going to say.

MS. KABBASH: Adam, I think in instructions you have appropriately instructed witnesses not to guess or speculate --

MR. SLATER: I didn't tell him that.

MS. KABBASH: -- and that's completely appropriate on your part, so I just want to reinforce that.

MR. SLATER: I didn't instruct him not to guess.
BY MR. SLATER:
Q. Let me ask you this. I'll ask you a fresh question.
One of the critical product assumptions was that this Prolift® would not create additional complications, and two examples given here are erosion and pain. Correct?
A. Yes. That's what is written.
Q. And was the feeling of the team that if the Prolift® was creating erosions and pain, that that would be a problem?
MS. KABBASH: Objection.
THE WITNESS: Well, let's go back to my answer. Well, I was not at this meeting. I don't understand very well what is additional complication. Additional to what? To what is existing? To what is known? I don't know.
BY MR. SLATER:
Q. Well, this presentation was e-mailed to you on June 18, 2003, the draft was, and on page 24, that exact language appears.
If you had read it, what would you --
If you had a concern about that

language, would you have brought that to someone's attention?
A. You mentioned page 24?
Q. What I'm saying is, that language that I just showed you was provided to you on June 18, a week before this document was finalized.
A. Yes. Well, I can't answer that. You know, when I receive such a document, I might read it, might not read it. If I read it, if I see something that is completely wrong on a medical standpoint, then I'm going to write and say, well, there is on page 35 something completely wrong.
But in this case, you know, no additional complication, my -- it seemed obvious for me to understand that we do not want this product to dramatically increase the risk of erosion, of complication, which is a fair assumption. So no reason for me to write to the author and say, well, look, there is something unclear there, you know.
Q. You certainly felt throughout this that if it turned out that with the Prolift®, there were high levels of erosion or women suffering from very significant chronic disabling pain, that would have been of great concern to you. Right?
A. Well, that's something I need to make

clear. When we develop something, we do not develop that to see a lot of people having big trouble. So erosion, well, most of the time, it is a complication that is minimum, not all the time, but most of the time. So -- and, you know, we were aware of these erosions. But it was -- you know, this was not considered by the experts what a large experience as a project killer, because erosion was seen by the team as, well, a postoperative problem but which, in most of the cases, was something that was easily managed by the doctor.
Q. Were you aware that there were some women that would get multiple recurrence erosions that would not be easily managed? Were you aware that that would happen to some women?
A. Well, what we knew at that time was what Dr. Cosson was telling us. He made a presentation saying, well, erosion in 75 percent of the cases are going to be cured by the first excision. And so in 25 percent, it's not going to be cured and there will be a new excision and the repair, and that will, again, cure a majority of the patient. So, of course, like everywhere in surgery, there might be situation where something that is usually minimal could become a bit more severe.

Q. Did you ever make an effort to -- well, rephrase.
You knew that the Prolift® was intended to go into a woman's body permanently. Right?
A. Yes.
Q. And you knew that the risk of erosion was not just a short-term risk, but it was a lifetime risk. Correct?
MS. KABBASH: Objection.
THE WITNESS: Well, no. It was considered by the expert as a postoperative complication, not something that's going to occur ten years after.
BY MR. SLATER:
Q. That's what your understanding was at the time?
A. Yes.
Q. Did you later come to learn that that understanding was incorrect and that erosions could occur years and years after the Prolift® would be placed in a woman's body?
A. Yes. Of course, you know -- let's take infection of meshes. This is something that occur most of the time post-operatively, but there

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have been description of cases where the infection can occur 20 years after during an infection.

So as a doctor, what we considered was erosion, this is something that is essentially a postoperative complication, a wound healing problem. And the fact it could occur long term after the procedure is something we can think about, but, you know, what the expert, including Jacquetin, whether long-term experience, it didn't see that as a major issue. So if it is occur in one patient out of one million, well, that's part of surgery. You know, in surgery you can have long-term complication. But we had sufficient confidence from Jacquetin experience, he has been using meshes for more than 10, 20 years, all his lifelong years he has been using them.

Jacquetin was a very honest guy. If -- he would not have hidden and would never have entered this project if he was convinced that meshes could lead to erosion on the long term and that would be a big issue, you know. So we had to rely on the experts.

Q. So you relied on Prof. Jacquetin, as you said, for the understanding that erosions with this material, with this procedure, from your perspective, was not a big concern?

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MS. KABBASH: Objection.

THE WITNESS: We didn't all rely on Jacquetin only. We relied on a pool of surgeon with experience with meshes.

BY MR. SLATER:

Q. You just told me for a while that you relied on Jacquetin with his experience using meshes. That was a very important factor in making your decisions as to whether or not this was a safe product. Right?

A. Yeah, let me correct. I mention Jacquetin because he's the oldest of the group. He has probably the longest experience. But many of the others had been using meshes for a very long time. And, you know, when you develop a project, you need to rely on the experts. I'm not an expert.

Q. Well, the other thing you could rely on is you could have done long-term clinical studies with the Prolift® to see whether and to what extent there would have been a long-term risk of erosion. You could have done that before you launched the product but chose not to. Right?

MS. KABBASH: Objection.

THE WITNESS: You know --

BY MR. SLATER:

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Q. Isn't that true? Is the answer to my question yes?

MS. KABBASH: Let him answer the question.

MR. SLATER: Well, it's a yes or no question.

THE WITNESS: This is -- no, it's not a yes or no question.

BY MR. SLATER:

Q. It is, though, because I'm asking you yes or no. So I'm --

MS. KABBASH: He's explained to you that he believes it's not a yes or no.

MR. SLATER: I'm going to withdraw the question and ask it again.

BY MR. SLATER:

Q. One of the things you could have done before you launched the Prolift® would have been to have a long-term clinical study done with the Prolift® before you launched it. That was an option you had. Correct?

MS. KABBASH: Objection.

THE WITNESS: Ideally in a medical device industry, you could always think about long term; but long term, what does that mean? Are we

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going to run a study for 20 years? It's just -- ideal world, but we need to be in some way realistic. We had expert telling us we have been using meshes for years and we are still using them. So if they are still using them, it means that they are not as an expert afraid of this complication. Point number one.

We are long-term experience of a sling being in the pelvic floor with -- for urinary incontinence. You know, the experience of Ulmsten was back from 1995. So at some point, you know, the company can say, well, I'm going to set up a trial for the next 20 years, but that's not very realistic in our world.

BY MR. SLATER:

Q. Do I understand you correctly --

MR. SLATER: Well, let me move to strike first that long answer.

BY MR. SLATER:

Q. Before you launched the Prolift®, was it your understanding that the risk of erosion was a short-term risk and was not a long-term risk, erosion of the mesh you were going to use in the Prolift®? Was that your understanding?

A. Yes.

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Q. If Prof. Jacquetin had informed you that he was concerned that the Prolift®, as it was going to be marketed with the Gynemesh® PS mesh, presented too high a risk of erosion and that the material needed to be changed, and if you knew that before you launched the Prolift®, would you have waited to launch the Prolift® to try to develop a better material before putting it in women's bodies?

MS. KABBASH: Objection.

THE WITNESS: If this would have been the case, you know, if the experts would have told me, Dr. Arnaud, the material is not appropriate but you're about to launch, you know what I would have done? I would have informed my company at the best level of the -- what Jacquetin told me. And after, the company takes the decision. But as a medical doctor, I would have said, wait, stop, alert. The team in France is alerting that the material is inadequate. That's what I would have done.

BY MR. SLATER:

Q. If Prof. Jacquetin had told you that the material that was going to be used in the Prolift®, the Gynemesh® PS, from his perspective would need to be replaced as soon as possible, if he said, you know, I'm okay with you launching the

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product, but I just want you to know, we need to get a better material here, would you, as a medical doctor looking out for the safety of patients, have said, you know what, in that case, let's not launch the product so quick, let's figure out if there's a better material we have available to us, and even if it takes a little more time, it's better to launch it with the safest material we have, would you have made that decision?

MS. KABBASH: Objection.

THE WITNESS: Okay. Let me be clear on this. If Prof. Jacquetin would have told me, we have plenty of complication with this matter, there is something wrong, you shouldn't have launched the product. This is one point.

Now, if Dr. Jacquetin would have told me, well, you know, we still have some erosion, we need to think about a next generation of material, that wouldn't have shocked me, because I've heard forever, you know, the surgeon, any time the procedure lead to a complication, saying, well, we need to think about a new generation of material, because the dream -- their dream is that with a new material, everything will disappear.

But as I told them very often, what

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is important in the mechanism of erosion, for example, is to understand what is the mechanism of erosion. Is it because they incise the vagina not deeply enough, for example? Or is it mesh related? Because if it is related to the surgical technique, we can change the mesh 20 times, they will not change the rate of erosion.

So I don't know if my answer is a little bit too complex, but, you know, as long as we don't know what is the mechanism of a complication, we cannot go blindly and change the mesh, change the mesh. So that's why Jacquetin would not have told me we need absolutely a new mesh. He might have told me, but I would have told him, well, dear professor, first of all, we -- you should give me confidence that you have fixed all the surgical problem, that it is a reasonable -- it is reasonable to think that some other material could be better. But so far, there is no reason to believe that the polypropylene mesh we were using could be replaced by something significantly better.

MR. SLATER: Move to strike.

BY MR. SLATER:

Q. When you launched the Prolift®, you did not understand the mechanism of erosion.

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Correct?

MS. KABBASH: Objection.

THE WITNESS: When we launched the Prolift®, we have different -- we are --

BY MR. SLATER:

Q. You had theories, but you didn't understand it. Correct?

A. Yeah, theories, but in medicine, there are so many area where everything is based on theory, because if we knew the truth all the time in medicine, that would be very simple. But in medicine, very often, you have to make assumptions.

So erosion could have three mechanisms. So we knew the three of them.

MR. SLATER: Can you read back the beginning of that answer, please, for me, Ann Marie? After I said it was a theory.

- - -

(The court reporter read the pertinent part of the record.)

- - -

MS. KABBASH: Adam, we're getting --

MR. SLATER: I'm going to finish this document. It will take a few more minutes, but I'm finishing this document. I'm not leaving it open.

BY MR. SLATER:
Q. At the time the Prolift® was launched, you had several theories of mechanisms that could lead to erosion, but you didn't feel confident that you understood the mechanism of erosion.
Is that a true statement?
MS. KABBASH: Objection.
THE WITNESS: By the time we launched this product, we were considering erosion as a complication that occurred in about 10 percent of the cases and which was not in the vast majority of the case a big issue. So when you put it in the balance, because surgery is always a matter of balance between the risk and the benefit. When you put it in the balance of the risk in front of the benefits, which is less recurrence, we were considering this was an acceptable complication.
So now, if based on that, if we could, of course, find a way to move from 10 percent to 0 percent, that would have been wonderful. So we tried to make our best efforts to understand the mechanism of erosion. And we had only theory for sure, because we don't know the truth, why is there an erosion. There are different explanation. But,

again, this was considered as an acceptable risk, because in most of the cases was a minor complication.
MR. SLATER: Move to strike.
Ann Marie, can you read my question back?
BY MR. SLATER:
Q. I'm just going to ask you if you could, Doctor, I think you could probably answer with a yes or a no. I'm going to ask you to do that if you can. Okay? She's going to read the question back to you again.
- - -
(The court reporter read the pertinent part of the record.)
- - -
MS. KABBASH: Objection.
THE WITNESS: My answer is erosion was an acceptable minor complication most of the time. And the fact we did not understand perfectly the mechanism of erosion was not considered as a major issue because we were addressing a complication that was acceptable in the benefit/risk balance.
MR. SLATER: Move to strike.

I'm going to ask the question be read back again and ask you to answer it, please.
- - -
(The court reporter read the pertinent part of the record.)
- - -
MS. KABBASH: Objection.
THE WITNESS: We did not understand the mechanism of erosion. Also, we have the three options.
BY MR. SLATER:
Q. Turn to page 36 of the PowerPoint, the final PowerPoint that was presented to the stagegate committee on June 27, 2003.
MS. KABBASH: The final page, you said?
MR. SLATER: Page 36.
BY MR. SLATER:
Q. It's titled "Critical Assumptions: Market."
Do you see that?
A. This one. Okay.
Q. And the first critical assumption for marketing was, "Product Features Will Justify A Premium Price As Compared To GYNEMESH PS Sheets."

That was one of the critical assumptions. Correct?
A. Yes.
Q. The second one listed here is, "Multiple Kits Will Be Required To Fully Exploit" the "Market."
Do you see that?
A. Yes.
Q. And one of the goals of your company was to fully exploit the market for the sale of mesh for pelvic floor repair. Correct?
MS. KABBASH: Objection.
THE WITNESS: Fully exploit the market means that if you -- if the market wants only anterior or only posterior and you come on the market with a total one, you're not going to satisfy the market. And there was a big difference between the philosophy of this repair in the different countries.
BY MR. SLATER:
Q. Let's look at the next page, page 37. This is the "Risk Assessment."
Do you see this?
A. Yes.
Q. This is the risk assessment at the

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time of stagegate presentation, June 27, 2003. And I'm going to go to the third one.

Do you see the third one? "Erosion/Recurrences due to mesh used."

Do you see that?

A. Yes.

Q. And the probability of that risk occurring was rated as an M, which would mean medium. Right?

A. Yes.

Q. And the impact in terms of what that would do to the project was described, "Need to go back into Concept Stage. Delayed launch and increased resources."

Do you see that?

A. Yes.

Q. So it's saying here that if there were erosion and recurrences due to the mesh used, due to the material itself, you would need to go back into the concept stage, delay launch, increase resources and essentially figure out if there's another material to use. Correct?

MS. KABBASH: Objection.

THE WITNESS: Well, that's not my vision, you know, because erosion --

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BY MR. SLATER:

Q. That's what it says in this presentation. Right?

A. Yes, yes. You know, the presentation probability is medium. So we knew that erosion would not -- would very likely to be part of the complication of this procedure.

Q. But that's not what it says here. It says, the risk that erosion or recurrences are due to the mesh used, due to the material. And if that were to occur, the impact was to go back to the concept stage, delay launch, increase resources and to continue to study. Right?

MS. KABBASH: Objection.

THE WITNESS: My understanding is that if we knew that there was an erosion rate which was considered acceptable, let's say 10 percent. Now, if we developed this project and we end up with 40 percent erosion, that means we need to go back to the concept stage because we have increased the erosion rate, the product has increased the erosion rate that is new and accepted by too much. And we need to go back to the concept. That's what it means.

BY MR. SLATER:

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Q. What if the erosion rate that you saw in clinical study was 30 percent? Would that have been too high?

MS. KABBASH: Objection.

THE WITNESS: Well, 30 percent, that's high. But the experience of most of the surgeon was something in between 5 and 10 percent.

BY MR. SLATER:

Q. If you saw in clinical study with this mesh material, the Gynemesh® PS with the TVM procedure, an erosion rate of 25 percent, would that have been too high and would you have had to go back to the concept stage?

MS. KABBASH: Objection.

THE WITNESS: If I would see a surgeon telling me I have 25 percent erosion rate, I would have paid him a visit to try to understand why he has an excessive erosion rate, because 25 for a single surgeon is more than the average.

BY MR. SLATER:

Q. If the -- rephrase.

If there was a clinical study with the TVM technique and Gynemesh® PS being used, and the erosion rate was 20 percent, would that have been too high to be acceptable to you?

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MS. KABBASH: Objection.

THE WITNESS: You know, it's difficult to talk about numbers, but 20 percent is still acceptable.

BY MR. SLATER:

Q. Acceptable to who?

MS. KABBASH: Objection.

BY MR. SLATER:

Q. Well, let me rephrase that.

20 percent would be acceptable to you? A 20 percent erosion rate with the Prolift® would be acceptable to you?

MS. KABBASH: Objection.

THE WITNESS: You know, 5 percent is great. 10 percent is the average. 20 percent is the upper limit. Now, if someone had 50 percent, there is something wrong. We need to understand why.

BY MR. SLATER:

Q. Well, let's talk about 20 percent.

If the very top surgeons in the world, the best at performing the TVM procedure, people like Prof. Jacquetin and his group, if they were getting -- with the TVM technique and Gynemesh® PS mesh, if they were getting an erosion rate of

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20 percent or more, if had you seen those rates, would you have said, this is a product we should not market, we need to continue to study it before we put it on the market, where there's going to be surgeons who are not going to be as skilled as them who would likely have higher erosion rates? Is that the decision you would have made if you saw those rates?

MS. KABBASH: Objection.

THE WITNESS: Well, I cannot speculate about the decision.

BY MR. SLATER:

Q. Well, I want you to tell me what you would have done knowing everything you knew before you launched the Prolift®, if those were the rates of erosion you saw with people like Prof. Jacquetin, the best in the world at performing this, would you have said, we don't -- we shouldn't launch this, we should wait?

MS. KABBASH: Objection.

BY MR. SLATER:

Q. It's a straightforward question. I'd like a yes or no answer, please.

A. Yes. No. You won't get it from me, but what I want to tell you is, first of all,

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20 percent, I think that's what we got in the first two clinical trials, something around 20 percent. But we need to consider that you are talking about the best experts in the world, but the best expert in the world in their early phase of performing a new procedure. So 20 percent with great expert, but great expert with a new procedure, they are still beginners. Now, a couple of years after the same -- you know the Altman study. The Altman study showed that the rate in the hands of all surgeon in Scandinavia was 3 percent, so --

Q. Doctor, I don't mean to interrupt you, but the tape is about to end, and I really -- I asked you a very simple question.

If Prof. Jacquetin and his group in 2004 were getting 20 percent erosion rates, and you would have known that other surgeons not as skilled would end up likely with higher rates, would you have said, this is not safe enough, I advocate we don't launch yet, yes or no?

MS. KABBASH: Objection.

THE WITNESS: 20 percent, in the hands of beginners?

BY MR. SLATER:

Q. Jacquetin in 2004.

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A. Jacquetin in 2004 was using a brand new product with brand new tools, and -- well, he was not a beginner, but he was in some way a beginner with the new material.

But 20 percent, I tell you we observed it and we continued the project, because we had very good -- very good -- we have very good indication this was going to decrease.

MR. SLATER: Move to strike.

He has to change the tape.

THE VIDEOGRAPHER: The time is now 1:23. We are going off the record.

MS. KABBASH: In light of that, Adam, I think that the witness needs some lunch. It's almost 1:30 now.

MR. SLATER: I'm finishing this document.

MS. KABBASH: Adam, you can finish the document after lunch. We've been going at this for three hours now. It's 1:30. We never go longer than this and let the witnesses not eat. So let's take a lunch break.

MR. SLATER: If you would like to take lunch, I'll take it. I can't stop you from leaving.

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MS. KABBASH: Good.

THE WITNESS: Let's take lunch then.

MS. KABBASH: I don't want Dr. Arnaud to go back to France and say those Americans didn't feed me.

- - -

(A luncheon recess was taken from 1:24 p.m. to 2:09 p.m.)

- - -

THE VIDEOGRAPHER: The time is now 2:09. This is the beginning of Disk Number 3. We are back on the record.

BY MR. SLATER:

Q. You would expect and you would have expected at the time of launch that surgeons not as accomplished or as experienced with the TVM technique as Dr. Jacquetin would have higher rates of complications and erosion. Correct?

MS. KABBASH: Objection.

THE WITNESS: Could you say that again? Sorry.

BY MR. SLATER:

Q. At the time of the launch of the Prolift®, did you expect that surgeons less experienced than Prof. Jacquetin and his group with

the Prolift® procedure would have higher rates of complications such as erosion?
A. Well, I think you're assuming that the surgical technique, the -- is related --
Q. I'm just asking a yes or no question.
A. Yes.
Q. I'm not assuming anything.
A. So it's no, because, you know --
Q. I didn't ask why.
A. -- we don't know.
MS. KABBASH: Adam, let him complete his question. You asked him to give complete and accurate answers. He's trying to do that.
MR. SLATER: Hang on. Hang on.
BY MR. SLATER:
Q. Look, if I ask for a yes or no and you go off and talk about something I didn't ask about, with all due respect, then I have to go and strike it and start over again, and I really -- I know you have to fly back to France tomorrow.
A. Okay.
Q. So in the interest of time, the attorneys sitting next to you can ask you questions at the end if they want to, and they can go into anything that they've -- you know, that they feel

like they need to cover with you or that they think you're eager to talk about. But I'm trying to focus the deposition so I can get through my question. That's all.
MS. KABBASH: And I appreciate that, Adam, but at the same time, he didn't even get to the point in his answer where we knew exactly what his answer was going to be.
MR. SLATER: I asked for yes or no, though, and so I was already going to strike the answer, so why bother.
MS. KABBASH: To allow him to answer the question.
MR. SLATER: Then I'm going to tell you right now, I don't guarantee you're going to make the flight tomorrow. If counsel is going to encourage you to give long answers that I didn't ask for, I'm just -- I'm trying to be as nice as I can about it, but I have to do my job.
THE WITNESS: I'll do my best.
BY MR. SLATER:
Q. Fair enough. That's all I could ask.
Let's look at the stagegate presentation, Exhibit 1258. Let's go to page 37. One of the risks identified is that the

"Procedures," meaning the Prolift® procedures, "do not gain acceptance among lesser-skilled" (non key opinion leader) "surgeons."
Do you see that?
A. Yes.
Q. The hope was that the Prolift® could be marketed not only to the highest skilled surgeons but also to the lesser skilled surgeons as well. Correct?
MS. KABBASH: Objection.
THE WITNESS: Yes.
BY MR. SLATER:
Q. And here it says, the probability of that would be low, but if it were to happen, the project would need to go back into the concept stage, delay the launch, increase resources, reevaluate the project.
That's what's written here. Correct?
A. Correct.
Q. And it says, the mitigation strategy would be to get VOC, voice of customer, from the non-key opinion leaders to find out why they have that viewpoint, that they're not accepting it, and aggressive marketing and professional education strategy. Correct?

A. Yes.
Q. So basically this is saying, if lesser-skilled surgeons are not adopting the Prolift®, one of the things we want to do is talk to them and find out why, and the other thing we want to do is market aggressively to them and also factor that into our professional education strategy. Correct?
MS. KABBASH: Objection.
THE WITNESS: Correct.
BY MR. SLATER:
Q. Did you believe that the Prolift® procedure was a complex procedure?
MS. KABBASH: Objection.
THE WITNESS: Yes. The Prolift® is rather complex if compared to the TVT®, for example. It's complex because you have three compartments to treat, and in the middle sometime you have the uterus still in place, sometimes you don't. So there is a lot of variation, which makes it a little bit more complex to -- of the whole picture, you know, for whole cases, while incontinence just very simple. It's just a standardized procedure. In most of the cases, there is no variation. In Prolift®, of course, is more complex because it's

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three procedure in one in some way.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. And I'll tell you, the reason I'm doing it is because if you keep feeding in testimony about the TVT®, which I have not asked you any questions about, I'm going to strike every single one of those answers. I understand that part of the preparation for this deposition was to have you talk as much as you could about the TVT® or maybe for whatever reason you are. This trial is about the Prolift®, and I'm going to keep striking answers that invoke your TVT® history. There will be a time and place for that, but that's what I'm striking in part your answer, because you're throwing in comparisons to the TVT®.
MS. KABBASH: Dr. Arnaud, I'm going to remind you, he can move to strike, he can do whatever he wants that he feels he needs to protect his legal rights. Your obligation is to answer the questions truthfully as best you can. So don't let his motions to strike be anything more than a legal procedure in this deposition. That's what they are. Okay? Thank you.
BY MR. SLATER:

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Q. As far as pelvic reconstructive procedures go, when the Prolift® went on the market, as compared to other procedures that were available, was it a complex procedure for prolapse repair?
A. Complex means that you make a comparison. It's more complex than a colporrhaphy probably. Is it -- it's probably -- is it more complex than the sacrocolpopexy? I don't know. Sacrocolpopexy is complex as well. So it is -- the level of complexity is somewhat in the range of sacrocolpopexy, I would say.
Q. You and your company certainly expected that a surgeon who was skilled and experienced in performing surgeries like abdominal sacrocolpopexy and colporrhaphy would be able to fully understand the Prolift® procedure. Correct?
MS. KABBASH: Objection.
THE WITNESS: Well, not really, because sacrocolpopexy in -- you know, there are two categories of surgeon. The one are more vaginalists and the ones that are more abdominalists, let's say, so -- at least in Europe, it's very rare to find a surgeon that is offering to his patient both approach. So the whole categorizing either vaginalist or abdominalist.

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So we were expecting that the vaginalist will -- are experienced, will cope quite easily with the procedure.
BY MR. SLATER:
Q. In your medical practice, you were a general and digestive surgeon. Correct?
A. Correct.
Q. You were not a gynecologist. Correct?
A. I was not.
Q. You did not treat gynecologic conditions. Correct?
A. Yes. No prolapse for sure.
Q. You did not perform urologic procedures. Correct?
A. Correct.
Q. You were able, when you were presented with this procedure, to understand it once it was presented to you, to understand what would be done. Correct?
A. Yes. I was a bit -- yes, because I have seen so many of them.
Q. Let's go to the risk assessment document.
The last risk, "Additional risk by

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obturator passage," that's referring to the risk that by making the obturator passes, there would be additional risks compared to other prolapse surgeries or compared to what?
MS. KABBASH: Objection.
THE WITNESS: It's comparing -- excuse me, for -- with TVT-O®. So TVT-O® you pass once and it's safe. But here, in Prolift®, we have to pass twice. So that the second passage may -- could have been a -- you know, an increased risk.
BY MR. SLATER:
Q. Were there any prolapse surgeries before the Prolift® came on the market where obturator passages would occur?
A. Well, of course, the Apogee®, Perigee®, the Apogee®. Otherwise, no. It was brand new.
Q. There were not obturator passages with colporrhaphy or ligament suspension. Correct?
A. Yes. Correct.
Q. If the obturator passages -- well, rephrase. Let me ask you this.
As compared to colporrhaphy, with or without uterosacral or sacrospinous ligament fixation, would there be more risk of injury due to

the obturator passages with the Prolift® simply by virtue of the fact that there weren't obturator passages with those other procedures?

MS. KABBASH: Objection.

THE WITNESS: I'm not sure I understand the question. Of course, if there is no passage in the obturator foramen, there is no risk specific to that.

BY MR. SLATER:

Q. So as compared to native tissue repairs, the obturator passages with the Prolift® introduced a new risk. Correct?

MS. KABBASH: Objection.

THE WITNESS: Yes. Of course, if you introduce two needles in the obturator foramen, you -- any time you pass a needle somewhere in the body, you introduce a risk.

BY MR. SLATER:

Q. These documents you can put aside.

I'm going to hand you an exhibit marked previously as Exhibit 620.

Exhibit 620 is two e-mails sent in July of 2003. In the first e-mail, Scott Ciarrocca writes to Prof. Jacquetin and Dr. Cosson, and he copies yourself, and basically asks about whether or

not Jacquetin and Cosson had seen slippage of the implants.

Do you see that?

And then in the response, Prof. Cosson responds and says he hasn't seen slippage of the implants as described by Scott Ciarrocca, and Prof. Cosson states, "The problems are more erosion, retraction."

Do you see that?

A. Yes.

Q. So certainly, as of July of 2003, if not before that, your company was on notice that with the use of the implants, the Gynemesh® implants being used with the TVM procedure, the problems they were seeing were erosion and retraction. Correct?

MS. KABBASH: Objection.

THE WITNESS: Yeah, that's correct. The erosion was not a surprise, you know. And retraction is a normal -- is a normal wound healing process. So nothing was really -- nothing was really a surprise for us.

BY MR. SLATER:

Q. Well, one of the things that you learned as this project went on was that retraction could cause significant complications for a patient.

Correct?

MS. KABBASH: Objection.

THE WITNESS: Well, we didn't learn that from the experience. That was already well known, you know, by vaginal surgeon, that anything you do through the vagina can lead to a retraction and sexual complication, because that's the function of the vagina. So we did not learn that due to this experience. We already knew that.

BY MR. SLATER:

Q. So you already knew that with the use of the Gynemesh® PS through the vagina, one of the potential risks was retraction of the mesh leading to pain with sexual intercourse. Correct?

A. Yeah. Any retraction, excessive retraction of the mesh, can lead to some local complication.

Q. And, actually, Prof. Cosson says, "It is possible to have a recurrence but it is usually due to a retraction of the mesh and the arms of the meshes are still in place even in those cases."

So he's saying, in his experience, recurrences are usually due to retraction of the Gynemesh®. Correct?

MS. KABBASH: Objection.

THE WITNESS: Well, that's, of course, a point that is important, you know. If the goal of the Prolift® is to create a mechanical barrier to all the possible defect, if the mesh retracts too much, it's not a mesh which retract -- if the tissue scarring lead to a retraction of the mesh and then the defect is not fully covered, then you have a risk of recurrence.

BY MR. SLATER:

Q. I'm going to hand you Exhibit 455.

Exhibit 455 is a series of three e-mails in February of 2004. And the first e-mail was from Scott Ciarrocca to Jacquetin and Cosson, again, you're copied, asking about tissue tearing.

Do you see that at the bottom of the page?

A. Yes.

Q. And Scott Ciarrocca says to them, "Since you became aware of the potential for tissue tearing during strap placement, have you been able to observe this phenomenon in surgery?"

And then Cosson responds, in the middle of the page, and we're going to put that up on the screen, one moment.

Prof. Cosson responds on February 5,

2004 to Scott Ciarrocca, and you're copied along with some others, with regard to tissue tearing during strap placement, "Yes many times unfortunately, with in these cases the problem of the mesh being to large at the end of the procedure, already shrinking...I think that it is a major concern."

Do you see that?

A. Yes.

Q. So first question, certainly you were aware that with placement of the straps with this procedure, the TVM procedure, tissue could be torn. Correct?

A. Correct.

Q. And that could cause, obviously, injury to a patient. Correct?

A. Yes. That's why we develop specific tool to put it in place.

Q. And he says that actually was happening many times, unfortunately. That's what --

A. Yes.

Q. -- Prof. Cosson says.

Then he says, "In these cases the problem of the mesh being to large at the end of the procedure, already shrinking...I think that it is a

major concern."

What is he referring to there?

A. I tried to understand. I don't -- I cannot. I don't know what he's saying, you know, the mesh already shrinking at the end of the procedure. That does not -- seems to be -- to make a lot of sense, because the mesh cannot shrink first, and at the end of the procedure, there is no wound healing. So I don't know what he's saying, but I know what they are talking about. They are talking about tearing the tissue during the strap placement.

Q. Now, let me ask you a few questions about this e-mail.

It was known by you that you were putting the Prolift® out when you marketed the Prolift®, the three different systems, the total, the anterior and the posterior. Correct?

A. Yes.

Q. And those systems each had one size. They were not sold in various sizes. Correct?

A. Yes.

Q. And you certainly knew that it would be necessary for surgeons to trim the mesh or cut the mesh back in some patients, because there may be

extra mesh or too much mesh, and the surgeon wouldn't want to leave the extra mesh. Correct?

A. Yes. It's normal practice if you feel the mesh is too large, you can cut a little bit of it.

Q. And it was understood that if the mesh were not to have a sufficient size, either because the person was large or because it had been cut too small, that if the mesh then contracted, that could lead to pain. Correct?

A. Yes. If the mesh contract and it pulls on fixed attachment, that would lead to pain. That's why we develop this concept of the strap going through the ligaments.

Q. Well, even with the straps going through the sacrospinous ligaments for support, if the mesh had been cut back too small and then contracted, you knew that could cause pain to a patient. Correct?

A. I'm not sure I understand, but, of course, if the mesh retracts and is not covering the wound defect, then you have a risk of recurrence.

Q. You also have a risk that once the mesh has now been incorporated into the pelvis, that if it retracts, it could then pull against nerves

and against tissue and could cause pain. Correct?

A. Yes. Well, I cannot speculate about the reason for pelvic pain. You have plenty of reason that can lead to pelvic pain, so --

Q. I'm not asking you to speculate. I'm asking about retraction of a Prolift® that had been cut back and now it's retracting even smaller. You knew that could cause pain to a patient. Right?

A. I don't understand what you mean. Because any time there is a retraction of the mesh, whether it has been cut back or not, it is something that is a potential source of pain among the others.

Q. So whether the mesh had been trimmed or not, it presents a risk that when there's retraction or contraction of the mesh, that can lead to pain for the patient. Correct?

A. Yeah. Any time there is -- the mesh pulls on this attachment, there is a potential risk of pain.

Q. At any time during the point -- well, rephrase.

At any time before the Prolift® was launched, did you attempt to study in any way whether there could be established a safe and effective way to remove Prolift® mesh, some or all

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of it, in the case that a patient had complications? Did you specifically study the question of what do you do to get the mesh out if it needs to be cut out of the woman's body because it's causing her complications?

MS. KABBASH: Objection.

THE WITNESS: Well, we did not specifically study this issue, but, of course, for the surgeons who were using Prolift® in the early stage, this was a question they had; because when you are a surgeon, you put something in the body, it is a normal question to think about what you would do if there was a complication. It's absolutely normal, you know, a surgeon think about what he would do if something goes wrong.

BY MR. SLATER:

Q. Ethicon, Gynecare, sold the Prolift® to be put into women's bodies. Correct?

A. Yes.

Q. Ethicon knew that for some of those women, some of the mesh, and in some of them maybe even all the mesh, would need to be removed if the women had complications. That was foreseeable. Right?

A. Well, I disagree with that, because

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if you have an erosion, you do not need to remove the mesh. If you have a retraction, what you need is try to fight against the fibrosis. So maybe a dilation, mechanical dilatation. Removing the mesh is something that would be a last resort.

Q. Did you know before the Prolift® was launched that there were going to be some patients for whom doctors would need to cut out some of the mesh and remove some of the mesh because the women either had retraction or had dyspareunia or had erosions? Did you know that?

A. Well, of course --

MS. KABBASH: Objection.

THE WITNESS: -- this is a general principle in surgery. Any time you put an implant, you should think about how to remove it if something goes wrong.

BY MR. SLATER:

Q. And as a manufacturer selling the Prolift®, Ethicon needed to think about that subject. Right?

MS. KABBASH: Objection.

THE WITNESS: Not specifically in this case, you know, because the kind of complication we had did not indicate that removal of

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the full mesh would be needed.

BY MR. SLATER:

Q. I didn't ask about the full mesh.

Any of the mesh. Part of the mesh. Did you ever think about, how can we give instructions -- well, rephrase.

With regard to removing part of the mesh, did you make any effort to try to establish whether it could be safe and effective for a surgeon to remove the parts of the mesh that would need to be removed, if that was what needed to be done? Did you even look at that subject and study it as a company --

MS. KABBASH: Objection.

BY MR. SLATER:

Q. -- before you sold the product to be paid for it? Did you even look at that subject?

MS. KABBASH: Objection.

THE WITNESS: My answer to you is, I know you don't want me to talk about slings, but let's talk about the slings --

BY MR. SLATER:

Q. Well, no. Let's talk about the Prolift®, with all due respect, because that's what my question is.

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A. Yes. But, you know, what we -- our way of thinking for Prolift® was absolutely derived from what we learned from slings. So it's very difficult for me to give you explanation without advocating what happened with slings.

Q. Well --

A. With slings, we never had to remove a sling. We had to cut the sling, we had to arrange the sling, but to remove the whole sling, I'm not aware of such case.

Q. Why do you keep saying remove the whole sling? I keep telling you my question is not limited to removing the entire mesh, it's trying to remove parts of it. So let me try to ask you a different question.

Did you know there were some women who would have contracted mesh that would cause pain and doctors would need to try to remove the part that was causing pain?

A. For sure. If mesh is responsible of something, and you need to remove part of it, it's just general surgery, you know. You make an incision and you dissect the mesh and you cut it.

Q. Did you think it was just a simple thing, a doctor could go in --

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A. Absolutely not.
Q. -- and easily remove the mesh?
A. No one could imagine it would be simple.
Q. Did you ever study the question of whether or not there was a safe and effective way to remove parts of the Prolift® if necessary after it was integrated, scarified, fibrosed? Did you ever look at that subject?
A. Of course we consider that.
Q. Okay.
How? Did you study it? If anyone studied it, tell me who studied that subject?
A. No. But, you know, studying a subject does not mean you are going to find a solution for it.
Q. Did you try to find a solution?
A. You know, for a surgeon, the solution is simple. You implant something.
Q. But I'm asking you. You were the person that was the lead of this entire effort to get the Prolift® out. You started it from day one. You were part of the company that sold the product and put it in people's hands to put in patients' bodies.

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So didn't you think you had a responsibility to try to figure out, well, if there's complications, can we tell the surgeons how to treat the complications safely with our product that we're going to be paid money for?
MS. KABBASH: Objection.
THE WITNESS: Well, I think my company has done a lot to -- in part, you know, Prof. Cosson, to let people know the type of complication, the way they should behave in professional education.
BY MR. SLATER:
Q. So tell me what specifically in professional education occurred that was sponsored by your copy reviewed professional education where doctors were explained, here's how you safely and effectively remove parts of the Prolift® mesh if there's a complication like a retraction, here's what you do. That didn't happen. Right?
A. No. What we did is --
Q. Is the answer to my question, that didn't happen?
A. What?
Q. What I just asked you, sir.
MS. KABBASH: Adam, you've asked him

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what has been done, and he's about to tell you what he believes has been done. So just let him complete his answer.
MR. SLATER: I just -- no, that's not what happened.
THE WITNESS: You asked me two questions. That's why.
BY MR. SLATER:
Q. Then fine. I will rephrase it.
Let's come back to the question I asked you before.
A. Okay.
Q. Neither the IFU, the surgical technique guide or anything that was provided with the product when someone would buy it, when the surgeon would actually get the product, explained here's how you can safely and effectively remove parts of the mesh if necessary if your patient has complications. Your company gave no information on that. Correct?
MS. KABBASH: Objection.
THE WITNESS: Well, you know, the role of a company is not to teach surgery to surgeon.
MR. SLATER: Move to strike.

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THE WITNESS: You know --
BY MR. SLATER:
Q. Am I accurate that your company gave no information on that subject?
A. My company did not give maybe this information in the IFU but made huge efforts to set up professional education in order for -- to -- for the experts like Prof. Cosson, who wrote articles in a journal about the classification of the complication and the way to manage the complication, because we knew as a company that management of the complication was part of the success of this procedure. Because an erosion is not a big deal most of the time, providing you explain to people how to manage them.
MR. SLATER: Can you read that back to me, please, Ann Marie?
- - -
(The court reporter read the pertinent part of the record.)
- - -
BY MR. SLATER:
Q. Part of the success of the procedure, as you called it, and as you marketed the Prolift®, was for the complications to be safely and

effectively manageable. Right?
A. Yes.
Q. And if complications that women were going to suffer would in some cases not be able to be safely and effectively managed, that would be a problem with the Prolift®. Correct?
MS. KABBASH: Objection.
THE WITNESS: Of course, if there were a huge complication, very important complication, that was not our goal in developing this procedure.
BY MR. SLATER:
Q. I've marked Exhibit 1259, which is an e-mail -- a couple e-mails in March of 2004.
- - -
(Deposition Exhibit No. Plaintiff's-1259, E-mail chain, top one dated 17 Mar 2004, Bates stamped ETH.MESH.03910637 and ETH.MESH.03910638, was marked for identification.)
- - -
BY MR. SLATER:
Q. In this e-mail, somebody named Wessel Van Dijk asked some questions of you.
Who was Wessel Van Dijk?

A. He was a guy from the Netherlands and I think was working for prof ed for Gynecare.
Q. And he asked you some questions that he called some critical customer questions having to do with Gynemesh® and this procedure. Correct?
A. Yes, yes.
Q. And you provided a response at the top of the page.
You provided your response at the top of the page. And I'm going to go through a little bit of what you told Mr. Van Dijk in March of 2004, about a year before the Prolift® was launched.
First, you talk about the differences between old and new Gynemesh®.
What are you talking about there?
A. I think at some point we had a product called Gynemesh®, which was a heavyweight polypropylene mesh, just a precut mesh of heavyweight polypropylene. And the new -- when I say new, is Gynemesh® PS. So the old one is heavy, the new one is light.
Q. One of the things you say, and I assume this would apply to Gynemesh® PS or the Prolift® or any mesh used for pelvic floor repair, correct me if I'm wrong, that you "need a product

which is as 'light' as possible." You put light in quotes. "The idea being to try to reduce the foreign body reaction as much as possible in order to avoid scar tissue." Am I correct?
A. Yes.
Q. And one of the goals with the Prolift® was to avoid scar tissue that would cause pain or other complications for the patient. Correct?
A. Yes.
Q. You say a little further down, "Erosion of the vagina is very common with any type of meshes." Right?
A. Right.
Q. When you say the word "erosion" there, are you using the word "erosion" to mean exposure? Are you saying it -- what do you -- rephrase.
When you use the word "erosion" there, what do you mean by that?
A. Well, for me, erosion and mesh exposure is just the same.
Q. So you're talking about when the mesh actually comes through and it's exposed into the vagina?

A. Yes. There is a loss of substance in the depth of which you can see the mesh.
Q. And you say here in your March 17, 2004 e-mail, "Erosion of the vagina," which you say is the same as exposure of the mesh into the vagina, "is very common with any type of meshes." Correct?
A. Yes.
Q. And that would hold true with the Prolift®. Correct?
A. Yes. Very common with any type of mesh.
Q. So if anybody were to say that the risk of the Prolift® mesh becoming exposed or eroding into the vagina is slight, that wouldn't be accurate, because as you state here, it's common. Correct?
MS. KABBASH: Objection.
THE WITNESS: Yes, it was common. Common means it's not rare.
BY MR. SLATER:
Q. You say a little below that, "Nobody really knows the precise mechanism by which it occurs," talking about erosion. Correct?
A. Yes.
Q. And you say, "It used to be viewed as

an infectious complication. It is more likely to be a vaginal wound dehiscence due to ischemia of the wound edges or infection."

Do you see that?

A. Yes.

Q. What are you referring to? Let's take it one at time. When you say "vaginal wound dehiscence," are you talking about at the site of the incision itself opening up?

A. Yes, yes.

Q. So you're saying when there is an erosion or an exposure into the vagina, it's more likely to be either due to the actual incision opening up and letting the mesh through or due to an infection of the mesh?

A. Yes.

Q. And when you talk about an infection of the mesh, what are you talking about?

A. Okay. You know, if you have an infection of the mesh, if you think theoretically you have an infection of the mesh, total infection with pus and the mesh being very easy to remove, being in the middle of the pus, that is something that is not what I'm talking about, because we did not observe that.

But you could think about, you know, a local infection, like you can have after a laparotomy, you can have a small partial infection of the wound. So what happened if you got that? Suddenly the pus goes out, and in laparotomy, you will see it. But in the vagina, you can imagine, there is a localized infection. And at some point the pus expel, no one see it, not even the patient, you know, a couple of cubic centimeter of pus. And then since it's open, it heals, because any time -- you know, when you have an abdominal infection, you just cut the suture. It opens. If you open the wound infection, you get cured.

So in my opinion was that there might be in a similar way as what I described for an abdominal incision, if you make a vaginal incision, you may have a localized infection that finally handled by an opening, which no one recognize because minor event. And then it get cured, it's cleaned. And at the end of the day, if you put a speculum and you look, you would find a hole and the mesh in the depths of the hole. So that was one of the possibility for explaining the erosion.

Q. And you said here, you thought it was likely that that was -- that if you have erosions

into the vagina, from your perspective, it's likely either because the incision actually opened up and let the mesh through or this process with infection that you just described would happen?

A. Yeah. First one is infection. Second one would be because during the incision, there is a kind of devascularization. So at the end of the day, when you suture the vagina, there is part of it which is not -- no longer vascularized. And most of the incision will heal, but there will be a kind of defect in the healing, because there is some kind of devascularization. So these are the two main mechanism. And why we do not believe that it could be kind of mechanical erosion, you know, with the vagina -- friction of the vagina on the mesh is because all the -- all the erosion are occurring in the line -- on the line of the incision. You know, if it was mechanical, it could be a side, but it is always on the line of the incision. So it's an issue with the incision. At the incision level, let's say.

Q. That's where it happens at the incision, and then the alternative would be where there's this infection that you described where --

A. Yes. Whether it's infection or a

lack of vascularization, it's always in the -- on the incision line.

Q. And what you're saying is where an infection would lead to an erosion into the vagina, you likely wouldn't see the evidence of the infection, you would just see the aftermath or the result, which would be the exposure of the mesh?

A. Sorry. I did not capture you.

Q. That's okay.

If I understood correctly, you're saying that if you have an infection of the mesh that leads to an exposure of the mesh into the vagina, you're saying you likely would not see any evidence of the infection, but, clinically, you would see the exposure of the mesh, and that's what tells you that this had occurred.

Am I understand you correctly?

A. If the theory of the infection is good, that's the way.

Q. And you certainly felt, at the time you wrote this e-mail, that that was -- you thought that was a accurate explanation. Correct?

A. At the time of this e-mail, I strongly believed it should be one of the two -- of the two, not another one.

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Q. And do you still feel that way?
A. Yes.
Q. And let me understand, if a woman were to have some sort of an opening in the vaginal skin, the vaginal covering --
A. Yes.
Q. -- that could allow bacteria to get through to the mesh, which could allow mesh to become infected and then could create an erosion into the vagina. Correct?
A. Not really, because when a mesh become infected, you can have a local infection or a whole infection of the mesh. But if this happened, but very likely it was not a whole infection, because otherwise, if you have a whole infection of the mesh, this is a major event, cannot be -- cannot go unknown, you know. The patient would have a fever, a lot of things. So it can only be a minor event, very localized; because if there was an infection of the whole mesh, then we would know.
Q. Did you have an understanding that you could get contamination of the Prolift® mesh and it could develop, maybe not a big, full-blown infection that would be apparent, but a chronic low-grade infection that could exist on the mesh?

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A. That's always a possibility with an implant, to have a kind of chronic infection, even if it's not been proven. It is something likely to -- possibility to occur with any implant, you know. Inguinal hernia, this might happen.
Q. And you wouldn't necessarily see any obvious signs of infection if that happened. It could just exist at a subclinical level?
A. That's what I think.
Q. Okay.
A. That's been my theory very often to say -- to try to explain why some center are more complication than others. I say, well, maybe there is a difference in the theater with regard to infection. Of course, it's speculation. It's -- you know, we try to understand why things are going, and we are obliged to make some hypotheses.
Q. Well, you've certainly studied the Prolift® and studied the complications and have focused on this, so to the best of your experience, that's what you think occurs. Correct?
A. Yes.
MR. SLATER: Go off the video for a second.
THE VIDEOGRAPHER: The time is now

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2:51. We are going off the record.
- - -
(A discussion off the record occurred.)
- - -
THE VIDEOGRAPHER: The time is now 2:59. We are back on the record.
BY MR. SLATER:
Q. In front of you is Exhibit 1181, which is two e-mails dated May 10, 2004. The first one was written by Ophelie Berthier.
Who is Ophelie Berthier?
A. She was the European product manager that was in charge of the commercialization of the Prolift®.
Q. That would be --
As a product manager, she would be somebody in the marketing department. Correct?
A. Yes.
Q. Ophelie Berthier, on May 10, 2004, wrote to Zenobia Walji, also in marketing in the United States, as well as Giselle Bonet in marketing, Gene Kammerer from research and development and yourself. And the subject, "Mesh for TVM." Right?

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A. Yes.
Q. I'm just going to put it up, highlight a bit of it, and I'm going to ask you about it.
Okay. The e-mail start -- I'm going to start over.
In the May 10, 2004 e-mail, Ophelie Berthier writes to yourself and the others, addresses obviously to Zenobia Walji in marketing, "I know you are working on new mesh materials with Gene and I'd like to share with you the inputs of Pr Jacquetin and Dr Cosson."
And Ophelie Berthier would have spoken directly with Jacquetin and Cosson periodically. Right?
A. Yes, yes. They were French people and Ophelie was based in France, so...
Q. And Gene is Gene Kammerer from research and development. Correct?
A. Yes.
Q. And this indicates that, with regards to Prof. Jacquetin and Dr. Cosson, "their main concern is now" --
I'll start over.
This e-mail indicates, with regards

to Prof. Jacquetin and Dr. Cosson, "Their main concern is now the shrinkage of the mesh which may lead to pain and dyspareunia...Indeed now that they have tremendously improved the technique and lowered the erosion rate what needs to be improved is the shrinkage of the mesh (in this case gynemesh soft)."

That's what she communicated per Jacquetin and Cosson. Correct?

A. Correct.

Q. And certainly as of May 2004, you were aware that you needed to find a way to either improve or reduce the rate or consequences of the shrinkage of the Gynemesh® Soft Mesh or to find another mesh material for the Prolift®. You were aware that that was something that needed to be accomplished. Correct?

MS. KABBASH: Objection.

THE WITNESS: Well, what this may says is we make big progress for erosion. Fine. So now the main concern is becoming shrinkage. Should get nothing very new. This e-mail is not saying we have discovered shrinkage can occur. It says, now that we have made progress in the erosion, advance, improvement, now the main concern becomes -- the number one concern becomes shrinkage.

Now, all this discussion about shrinkage and the mesh, again, is backed on the fact that people wrongly believed that the only thing that can prevent shrinkage is a new mesh. But this is not -- this is not a good way of thinking, you know. Before you can say a new mesh is going to improve the shrinkage, you should identify what is the mechanical -- mechanism of the shrinkage. It's sure that bad mesh can improve fibrosis and very likely improve the shrinkage, but this does not mean that by changing the mesh you are going to have less shrinkage.

BY MR. SLATER:

Q. You never in fact figured out a way to reduce the rates of shrinkage with the Prolift® when it used Gynemesh® Prolene® Soft Mesh. Right?

MS. KABBASH: Objection.

THE WITNESS: We always thought about that, but there is a difference between being aware of a potential issue and finding a solution. So finding a solution for shrinkage, shrinkage is made of -- is a natural -- no, sorry. There is a natural process of wound healing, which is always associated with shrinkage, whether you use a mesh or not. So the mesh in the worst case can aggravate the case.

But, you know, it does not mean that by changing the mesh, shrinkage is not going to occur.

BY MR. SLATER:

Q. In fact, your thinking at the time -- well, rephrase.

You knew at the time that shrinkage, as stated in this e-mail, could lead to pain. Correct?

A. That's not new. Shrinkage can lead to pain.

Q. And you knew that shrinkage could lead to dyspareunia. Correct? Shrinkage could lead to that. Correct?

A. Not new. The vagina is a cavity. If there's a shrinkage, the cavity can become smaller.

Q. You knew that shrinkage could lead to recurrence of the prolapse. Correct?

A. Correct.

Q. You knew that shrinkage could lead to erosion?

A. Well, for me, it's not obvious, no. Shrinkage and erosion, I don't know. Maybe, but -- no idea.

Q. You knew that shrinkage could lead to anatomic distortion of the vagina. Correct?

A. Yes.

Q. You knew that shrinkage of the mesh could lead to the need to operate on the patient again to try to remove part of the mesh. Correct?

A. In the worst case, possibly. It's a possibility.

Q. Well, you knew that would happen to some women?

A. Of course, because it's a possibility.

Q. You knew that for some women, they wouldn't just need one surgery to try to remove contracted mesh but that they could need to undergo multiple surgeries. Right? You knew that was something that could happen to some women. Right?

A. Well, you know, basically what I knew is that with any surgical procedure, we could have complication, and that could lead to reoperation.

Q. I'm asking about the Prolift® now.

And you knew with the Prolift® --

A. Of course we knew that if it is an operation, then there are possibility to reoperation.

Q. You knew with the Prolift® that when the mesh contracted and shrunk, that a woman could

go through one surgery and that -- to remove part of the mesh and that might not fix her and that some women in fact would need to undergo multiple surgeries in an effort to remove mesh that had contracted. You knew that would happen to some women. Correct?

A. Yeah. We knew that in the same way you knew any time you use a mesh, a graft, an implant, there might be complication and multiple need to -- for reoperation. That's not -- that was not new. That's just the rule of the game with all implants.

Q. And you knew that these complications that could occur due to contraction of the mesh could cause a woman's quality of life to be permanently damaged. Right?

MS. KABBASH: Objection.

BY MR. SLATER:

Q. Some women would have permanent damage to their quality of life. You knew that. Right?

MS. KABBASH: Objection.

THE WITNESS: Well, you know any time you go to surgery, you know that you can have complication.

BY MR. SLATER:

Q. Sir, I'm asking about Prolift®.

A. The Prolift® is a surgical procedure, so the complication are possible, like with every surgical procedure.

MR. SLATER: Move to strike.

BY MR. SLATER:

Q. You knew with the Prolift® that if a woman had contraction of the mesh, that the complications could lead to permanent damage to her quality of life. You knew for some women that would happen. Correct?

A. Not correct, because if you have a complication, you go and see your surgeon and you ask the surgeon to find a solution to your complication. So what you're saying is, you have a complication, so now it's forever. Well, if I have a complication after a procedure, I go back to my surgeon and ask him to try to correct the consequence of his procedure. So if I have big shrinkage after a procedure, I would visit my surgeon, say, Doctor, look, my vagina is a problem, what can you do for me. That's all I know.

Q. And you knew, as the scientific director for Gynecare when the Prolift® was going to

market, that for some women, regardless of how many surgeons they went to and how many procedures they had by surgeons who were trying to help them, that some of them would be left with permanent complications and permanent damage to their quality of life. Correct?

A. No. Well, I could not imagine such a worst case, even if in surgery you can always imagine the worst, the worst being the death. Of course, the worst can always happen, but, you know, I could not imagine that this would be something that is very common. It might happen, because any single surgical procedure can lead to complication. And some of them can be terrible, even an appendectomy, an amygdalectomy. So of course when you're developing a new procedure, you have to assume that at some point, there might be terrible complication, and the death is one of them. You know, any time you go for surgery, you can die from the anesthesiology.

So, of course, we knew that complication would occur, because this is related to any surgical procedure, so -- well, it may be that there will be very bad retraction and it could be -- you know, the surgeon always find a solution to the

complication, so...

Q. Is your testimony that the last thing you said, the surgeon always finds a solution to the complication?

A. With time.

Q. You knew that for some women, when they had contraction of the Prolift® mesh, despite a surgeon or multiple surgeons of very high skill levels, for some of those women, a solution would not be able to be found and they'd be left with permanent pain and permanent damage to their quality of life. Correct?

MS. KABBASH: Objection.

THE WITNESS: Yeah. But this is 2012 and we are talking about in 2004, so --

BY MR. SLATER:

Q. Well, you knew that --

A. -- it is always easier after eight years to say, oh, that's the situation. But when you are in 2000 -- if you had been in 2004, you know, we were -- our goal was to develop a good procedure for women all over the world.

And now you're telling me eight years after, oh, you know, some people have had terrible result. I can understand that, but, you know,

that's something that happen with any kind of surgery.

Q. Are you saying that when the Prolift® was launched, that you didn't know that some women would end up with the type of very serious, lifelong complications that I just described?

MS. KABBASH: Objection.

BY MR. SLATER:

Q. And that you only learned that over the course of time after the Prolift® had been on the market for years? Is that what you're telling me?

MS. KABBASH: Objection.

THE WITNESS: What I'm telling you is that when you are talking about surgery --

BY MR. SLATER:

Q. I'm talking about the Prolift®, and I asked you a specific question. I'd appreciate you answering that question, sir.

A. Okay. Prolift® is one of the surgical procedure. All surgical procedure can give complications. Some of them be minor, some of them being terrible. So why would I have thought in 2004 that Prolift® would be the only procedure in the world that would not give any severe complication?

Q. Nobody asked you that, with all due respect. I'm going to ask the court reporter to read my question back to you and just ask you to answer it directly, please.

A. Okay.

- - -

(The court reporter read the pertinent part of the record.)

- - -

THE WITNESS: Okay. Let me answer very precisely. I did not imagine that there would be sequelae, and when I mean sequelae, something that cannot be arranged, improved by anyone, that women would end up with a sequelae which is so severe that their life would be completely disturbed.

You know, because I and all the experts also believed that if something would occur, they would be able to find a solution. Otherwise, you know, these people are not -- they are honest individual, honest doctor, you know. If they are -- thought one second that they could really hurt very badly and forever women in a significant number, not in an exceptional case, they would not have supported us.

MR. SLATER: Ann Marie, can you read me back his answer. There's going to come a point when I'm going to move to strike, I just have to figure out which -- where I lost, because I lost track of the spot.

- - -

(The court reporter read the pertinent part of the record.)

- - -

MR. SLATER: I'm going to move to strike from the word "otherwise" forward.

BY MR. SLATER:

Q. So if I understand correctly, it was your assumption when the Prolift® was launched to the market in March of 2005 that to the extent a woman did have serious complications, that surgeons out there in the surgical community would figure out the way to treat those complications?

A. Yes.

MS. KABBASH: Objection.

BY MR. SLATER:

Q. What did Ethicon -- well, let me rephrase.

Before the Prolift® was launched, Ethicon did not figure out the methods that would be

able to safely and effectively treat women who had the very serious complications like we've been speaking about. Ethicon and you assumed that surgeons would develop those remedies as time went on.

Do I understand?

MS. KABBASH: Objection.

THE WITNESS: I understand what you mean.

BY MR. SLATER:

Q. Am I correct?

A. You're correct. If you're a medical device manufacturer, it's -- what can I say? It's not necessarily your role, you know, to find the solution for the complications of the surgical procedure. So if there is a retraction, what can a manufacturer do? Nothing. It's the surgeon who's going to resect the piece of the mesh. It's not the manufacturer. What can a manufacturer say? There's nothing we can do.

Q. The manufacturer could warn the surgeons and the patients and tell them there are some complications that are so severe, we can't tell you how to safely and effectively treat those, and there's no established way that we know of. You

could warn about that. Right?
A. Well, you know, what you are asking is should we warn that death is possible after a Prolift®? Because it's possible. You can die from the anesthesiology. Should we warn that a death is possible as a manufacturer? Or is it obvious that any time you have an anesthesiology, you can die?
Q. You warn in the IFU that there could be bleeding from the procedure, so why not warn that there are some women whose complications could be so severe that, at this point, you can't advise of a solution to fix that, that some of the solutions may not be able to be safely and effectively treated? If you're going to warn something as obvious as you can get bleeding, why not warn about the most catastrophic complications maybe being untreatable?
A. Because I told you, we are not imagining that the sequelae would be a possibility. Because if you have a contraction, you still have -- when you have a complication in surgery, you still have possibility to treat complication. The surgeon are able to treat complication.
So, of course, understand, you have had cases where there is a retraction. The woman has seen the best experts. And after multiple

procedures, she still have a problem. That's fine. But that's in 2012. In 2004, we might not imagine that this could happen.
Q. Well, let's not talk about might not.
The Prolift® went on the market, give or take, on March 10, 2005.
As of that day, as of when the Prolift® was going on the market, did your company realize that there were some women who would have these very serious complications, that despite multiple surgeries, multiple doctors trying to treat it, the women would not get better and they would end up with these very serious, permanent, life-altering damage?
A. In 2005 we could rely on the expert opinion --
Q. I'm asking if you knew it.
A. -- and the clinical data.
Q. I'm asking if you knew that.
Did you know it when the Prolift® was launched?
A. When the Prolift® was launched, what we knew was the expert opinion and the clinical data, we are in the clinical data, I don't think we heard any of these cases.

Q. I'm going to ask my question again.
Did you know that there were some women that would end up with these very serious complications that could not be treated, despite surgeons operating multiple times, despite multiple doctors trying, and that some women who would have Prolift® complications would be left with permanent, life-altering damage? Did you know that would happen to some women as of the day the Prolift® was launched? Did you know that would happen?
MS. KABBASH: Objection.
THE WITNESS: Well, we knew that -- what we knew, sorry, was that a retraction could occur, that this retraction could, in the worst case, have some consequence like dyspareunia, but we thought that this kind of complication would not be severe enough to reach what you are describing but would be a complication that would be managed in some way by a dilatation or by some kind of reoperation in the same way that the erosion were managed by a simple excision and a new suture.
So we were not imagining that the worst could happen. We are not thinking in that way. But, of course, you can always imagine the worst. We could imagine that some woman would have

died from the procedure. So, you know --
BY MR. SLATER:
Q. Did you learn over the course of time after the Prolift® went on the market that some women were having these very serious complications, that despite intensive treatment by very good doctors, the women couldn't get better and they were left with permanent, life-altering damage? Did you learn that over time that that was happening?
MS. KABBASH: Objection.
THE WITNESS: Well, you know, from 2008, I left Gynecare. But, of course, I knew that -- I know that any time you put the device in the hand of the entire world, there will be some complications somewhere. Now, I also know that it depends very much on the way it is performed. I also -- I also know that -- well, it depends very much on the way it is being performed.
BY MR. SLATER:
Q. Well, you knew that doctors of varying skill levels from varying backgrounds would do the Prolift® procedure. Right?
A. Yes.
Q. You knew some would be more skillful than others. Right?

A. That's a general rule in surgery. You know, you have good surgeon, bad surgeon.
Q. You knew that doctors would exercise surgical judgment from patient to patient based on, for example, anatomic variation. Correct?
A. Yes.
Q. You knew that in fact the patients would have anatomic variations from patient to patient and that could make the surgery more complicated. Right?
A. Yes. That's normal in surgery. You're not all the same.
Q. I'm talking about the Prolift® now.
And you knew that because of anatomic variations, that that could create complications for some patients. Correct?
A. No, not correct. Anatomic variation do not create complication to patient. It create difficulty for the surgeon, which is very different.
Q. Well, the more difficulty for the surgeon, the higher the risk of a complication. Correct?
A. Yes.
Q. So if you have anatomic variations that create difficulty, that will increase the risk

of complications. Correct?
MS. KABBASH: Objection.
THE WITNESS: You know, anatomic variation, that's part of the daily routine of the surgeon. You know, all patients are different, so why is that different for Prolift® and for appendectomy than for any procedure. Anatomic variation is like, you know, weather condition for the --
BY MR. SLATER:
Q. Well, I'll tell you how it's difficult.
With an appendectomy, there's a procedure a doctor performs and removes the appendix. With the Prolift®, they take the mesh and the instruments that your company sold, potentially for several thousand dollars, and puts it into a woman's body. So there's a difference between someone taking a product that your company puts out there and says this is a safe and effective product, you should put this into your patient's body, or says to the patient, you should let this be put in your body. There's a big difference between that and someone going in and having a surgical procedure performed where a manufacturer like Ethicon isn't

making money off the procedure being done.
Isn't there a big difference?
MS. KABBASH: Objection.
THE WITNESS: Yes. You make comparison that -- there is a difference, yes. There is a difference. We're not talking about the same thing.
BY MR. SLATER:
Q. And, therefore, your company had a responsibility to make sure, number one, before this Prolift® went on the market, that you had thoroughly studied it and understood the full range of complications before you would put it on the market and represent to patients and surgeons that you put your company's name behind it and said, this is a safe product, it's an effective product, and it will be safe for the rest of your life because it's permanent. You agree with that. Right? You needed to thoroughly study it before you made those representations. Right?
A. Well, I think when you say a product is safe and effective, are you going to say, nothing is going to happen with this?
Q. Well, you, in fact, didn't know what was going to happen with the Prolift®. Isn't that

what you're telling me? You didn't understand the mechanism of erosion. Right? You couldn't figure out a way to reduce shrinkage of the mesh. Right? Those are two things you've admitted to me. Right?
MS. KABBASH: Objection and objection.
THE WITNESS: Yes, yes.
BY MR. SLATER:
Q. And you didn't have an understanding about long-term consequences in terms of what complications women would actually suffer as the years went on. Correct?
MS. KABBASH: Objection.
BY MR. SLATER:
Q. You didn't know. Right?
A. We didn't know -- you know, when you are designing a product, when you are an inventor, you don't know what's going to happen in 20 years, because you don't have a crystal ball.
Q. And if you don't know, if you don't know why erosion happens, if you don't understand a way to reduce shrinkage, if you don't know what the long-term consequences are going to be, how do you put the product on the market, sir? How do you sell that to put into patients' bodies? Why don't you

just wait and study it for a while and learn about it so that you can really be sure about these things? Why not do that?

MS. KABBASH: Objection to this line of questioning as argumentative.

BY MR. SLATER:

Q. Why didn't you do?

A. I will answer as to that.

Q. Why didn't you do that?

MS. KABBASH: Objection.

THE WITNESS: You know, when you open the abdominal cavity, there is 15 percent risk of incisional hernia. 15 percent risk of incisional hernia. So if I understood you correctly, you should ask us, why didn't you study suture more then before you sell them to close the abdominal cavity. Because at some point, we need to close the abdominal cavity.

BY MR. SLATER:

Q. But your company didn't create that procedure. Surgeons created that procedure and used sutures as a part of that procedure. Your company sold the Prolift® procedure to the world. It's a big difference, isn't it?

MS. KABBASH: Objection.

THE WITNESS: Yeah, but our company --

BY MR. SLATER:

Q. Isn't it a big difference?

MS. KABBASH: Objection.

THE WITNESS: Our company did not create the procedure.

BY MR. SLATER:

Q. Your company sold the procedure.

A. A group of expert created a procedure.

Q. With your input, with your company creating the instruments for them, and your company sold it to make money. Right? It's a true statement. Right?

A. Our company --

MS. KABBASH: First of all, Adam, you're getting very argumentative. Second, let him finish his response before you ask him another question.

BY MR. SLATER:

Q. I'll ask you a clean question.

Your company took Prof. Jacquetin's work, and then together you developed this procedure over several years, and your company developed the

instruments and then your company sold the Prolift® as an integrated system to make money. So your company was going to profit from it and, frankly, all the surgeons that worked on this project with you also stood to gain notoriety and to make money as well. So all of you had a financial incentive as this went forward; isn't that true?

MS. KABBASH: Objection.

THE WITNESS: Well, that's a very, very bad vision of this project. This project was, essentially and first of all, developed to offer a solution as an alternative to a very bad result for other procedures. That's what was developed. It was not developed for Prof. Jacquetin, Group TVM to make money or Ethicon to make money. For the three years of this project, Ethicon was not even aware of my work with these people.

BY MR. SLATER:

Q. Let me ask you this.

When you put the product out on the market and you represented to surgeons and you represented to patients these are the risks of things that may happen to you, in reality, you really didn't understand the risks very well? Because it was so new, you really didn't understand

very well the risks. Right?

MS. KABBASH: Objection.

THE WITNESS: No. We perfectly understood that there was some risk. The erosion was not new for Jacquetin and his group, who had been using meshes for years, so --

BY MR. SLATER:

Q. But Dr. Arnaud --

MS. KABBASH: Let him finish.

THE WITNESS: -- erosion was well known.

BY MR. SLATER:

Q. It was well known to this group, but they didn't even understand why it was happening?

MS. KABBASH: Objection.

THE WITNESS: Well, you know, very often in medicine, you can imagine in surgery, the number of situation where you have complication. And after half a century, you still do not know why you have this complication.

BY MR. SLATER:

Q. But in this case, rather than you sitting there and staying out of it, your company got involved and mass marketed their procedure. There's a big difference than Jacquetin as a doctor

experimenting or doing whatever he was doing off in his hospital in France, it's very different than your company buying the assignment of the patent and selling the product on a mass basis throughout the world.

Isn't it very different?

MS. KABBASH: Objection.

BY MR. SLATER:

Q. You put it in --

Because of your company's work, it went into my clients' bodies. It wouldn't have otherwise.

MS. KABBASH: Objection.

BY MR. SLATER:

Q. Isn't your company a big player in this?

MS. KABBASH: Objection.

BY MR. SLATER:

Q. Don't you have a role?

MS. KABBASH: Objection as argumentative, asked and answered.

BY MR. SLATER:

Q. Do you agree with me?

A. You know, very frankly, what I can say is erosion, we knew. Retraction, we knew. I

don't think we have -- I have done anything to anyone, and our role was not -- because we're only focused on those case who have had very bad result But there are also a lot of people who have benefitted from this procedure. And in front of that, you know, if you take colporrhaphies, the gold standard, colporrhaphies there is also complication and has a very high rate of recurrence. And when you have a recurrence, you take a reoperation, you take a new risk, and you can also have a lot of complication with this procedure.

So I understand that now you're telling me I'm a very bad boy, should never have done that, but I do not feel guilty, because I feel that we have offered to the world a procedure. Maybe things have not gone perfectly well, but, you know, we are not -- I have done anything, we have tried to do our best not to make money, but, first of all, as a doctor, as this group of TVM are doctors, they are absolutely not interested in the money they would make. They have done this work three years, meeting all over the time and never receiving a single Euro from us. And while -- I think the vision you are giving is not representative of what happened.

MR. SLATER: Let's take a break.

THE VIDEOGRAPHER: The time is now 3:31. This is the end of Disk Number 3. We are now off the record.

- - -

(A recess was taken from 3:31 p.m. to 3:48 p.m.)

- - -

THE VIDEOGRAPHER: The time is now 3:48. We are back on the record.

BY MR. SLATER:

Q. I've given you Exhibit 3005, which is a July 16, 2004 e-mail from Laura Angelini, who you've told me is from marketing, and it was sent to several people, including yourself. Correct?

A. Yes.

Q. The subject line says, "D'Art." Or is it D'Art? How do you pronounce that?

A. D'Art.

Q. D'Art.

A. D'Art.

MS. KABBASH: By far says it better than any other witness in this litigation.

MR. SLATER: I'm now going to start over. Rephrase.

BY MR. SLATER:

Q. Now I'm looking at Exhibit 3005 that you have in front of you. It's a July 16, 2004 e-mail from Laura Angelini to yourself and several others regarding "D'Art - Conversation with Prof. Jacquetin."

And what is that, D'Art? What does that signify?

A. D'Art is one of the nickname of the project I see of the Prolift®.

MS. KABBASH: Oh, I'm sorry. I think we have to --

BY MR. SLATER:

Q. And Laura Angelini in this e-mail starts off, "Dear All, This is to let you know that today I had a phone conversation with Prof. Jacquetin regarding some of the recent information that have been circulating on TVM."

And it's a long e-mail, but I'm going to just draw your attention to a couple specific things. If you go a little bit more than halfway down, there's a sentence that starts, "In particular." So if you go about halfway down, and it's just to the right of the middle of the page, it says, "In particular." And it's up on the screen as

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well.
A. Okay.
Q. And Laura Angelini says, per Prof. Jacquetin, July 2004, "In particular, in his opinion we should focus on reducing the stiffness of the area after the incorporation of the material and the shrinking effect. What he is really aiming at (i.e. the unmet need) is to ensure a good sexual activity post surgery especially considering that young women might go into prolapse repair."
Do you see that?
A. Yes.
Q. So that was what he was focusing, this should be the focus going forward. Correct?
A. Correct.
Q. And then if you go down a little bit further, it says, about five lines further down, six lines further down, "He wants us to launch TVM but remain open to look immediately into what can be improved and be proactive and not reactive about that. And he feels that improvement in the materials is what the next frontier is."
Do you see that?
A. Yes.
Q. And you certainly knew that, that was

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Prof. Jacquetin's feeling at that time. Correct?
A. Yes, yes.
Q. And would you agree with me, that was also your feeling, that there was a need to improve the material, the mesh material, in the Prolift® or in the product that you were developing that ultimately was launched as the Prolift® about eight months later?
A. Yes. Providing everything is not perfect, you always have a need to improve.
Q. Well, you knew here, about eight months before the Prolift® was actually launched, that there was already a need to improve the mesh material in order to reduce the stiffness of the area of the implant after the material would be incorporated with the body and after the scar tissue would form and the shrinkage would happen. Correct?
A. Yeah, that's correct.
Q. And if in fact it turned out that you couldn't improve that and you couldn't reduce the shrinking effect, that would have been something you would have had to take into consideration as you went forward and say, well, if we can't reduce this, maybe that's a reason that we should go a different direction. Right?

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MS. KABBASH: Objection.
THE WITNESS: What he's saying, he's saying, well, I'm fine with the erosion now, and, of course, again, since there are two complication, erosion and shrinkage, so if he's happy with erosion, he moves to shrinkage, because everybody in life wants to have something perfect. So in his mind, it seems from what he wrote that he was okay with putting the product on the market, but he was emphasizing that we should in the future -- where we should in the future try to improve the product. And he knew that improving a product was not a matter of a couple of weeks or months. It could take years.
So what I take of this message is, fine, it can go on the market, but we should start to look for a better material. And I put better in brackets, because in the mind of the doctors, since they were not able to find -- to improve the technique, it mean for them that probably the issue was coming from the material, which, again, as a deduction is not necessarily right.
So Prof. Jacquetin is an idealist guy, and he is never satisfied unless he got the perfection. So he's telling us, well, guys, you

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should work on the new material, but, you know, I was not really 100 percent convinced that any change in the material would lead to no shrinkage. Why is that? It's because shrinkage is normal. Shrinkage of a wound is a normal way of healing. You know, any wound in the body heal with shrinkage, so --
BY MR. SLATER:
Q. But when you have mesh there, it's a very different phenomenon, isn't it?
A. That's what you say, but are you sure about that?
Q. Well, isn't it?
MS. KABBASH: Objection.
BY MR. SLATER:
Q. If you put the mesh in, and the mesh is all around the vagina and the bladder and all within the pelvis, and the natural healing is not just limited to where incisions were made but actually is -- you have an inflammatory reaction, which is with the entire mesh. And that's what happens. Right?
A. That's what you say.
Q. Well, that's what you know, isn't it?
A. No. I don't know.
Q. You don't believe --

A. I know very little. You know, I'm more a --
Q. Well, I'm going to show you the documents, Doctor. I mean, so let's make this simple.
You know that the Prolift® mesh incites a chronic inflammatory reaction throughout where the Prolift® mesh is, and it's not limited just to the incision sites, it's throughout where the mesh is in the body. That's happening, so the body is scarring all around all of the mesh, integrating all the mesh, wherever it is in the pelvis. That's true, isn't it?
MS. KABBASH: Objection.
THE WITNESS: I don't know.
BY MR. SLATER:
Q. Well, how else is the mesh going to become integrated and develop a scar net if it's not happening across all of the mesh? It has to happen with all the mesh, doesn't it?
A. I cannot follow you on that, you know. It's intimate process of wound healing. You are making some assumption. And, well, we need more detailed discussion on that. I'm not saying you are wrong, but I'm saying, well, I don't know -- I don't

really understand what you're saying.
Q. Well, a moment ago you said that this was his viewpoint, he's an idealist about switching the material. But look at the e-mail again.
A. Yes.
Q. Look at the e-mail. Right below what I just read. "He feels that improvement in the materials is what the next frontier is." That's right below where he says, "Remain open to look immediately into what can be improved and...proactive about that."
Look at what Laura Angelini says right below that. "I have mentioned that we agree with him and actually we are already working in that sense. Gene," meaning Gene Kammerer, "I mentioned that you run this effort for Gynecare and offered him to meet you during ICS."
In fact, Gene Kammerer was already working on and looking at the potential that Ultrapro® mesh could have lower rates of erosion and lower rates of contraction if used in the Prolift® than Gynemesh® PS. He was already looking at that, wasn't he?
A. Yeah. Isn't that normal, that a company, knowing that there are -- there are some

reasons that are not perfect is working for a next generation in order to improve these things. But Gene was working on that. But, you know, there is no guarantee that at some point, it will change anything to the picture, because this is, again, with the assumption that the material at the end of the day was important. And that's something I'm not sure about. I do not agree with Jacquetin. You know, on a scientific basis, you need to know the mechanism. And while it's nice to say Prof. Jacquetin feel that by changing the material we are going to change the way it work, but if I go in the upper part of the message, you know, what he's saying, he's saying, well, now I have a new material, the Prolene® Soft, and the Prolene® Soft I'm very happy, because the erosion rate has decreased. Nevertheless, I don't know if this is due to the new material or this -- or whether this is due to my improved technique.
Q. Well, shouldn't you, as a company that's going to sell the product, learn the answers to these questions before you put the product on the market and sell it? Don't you have a responsibility to understand what's happening with your product and your system before you sell it?

MS. KABBASH: Objection.
THE WITNESS: To what question are you talking about?
BY MR. SLATER:
Q. Well, let's look at what we specifically were talking about here. Let me withdraw that and I'll ask you a new question.
This is eight months before the Prolift® was ever launched. So it's not like the product was on the market and then somebody came up with the idea, hey, there's a way to improve the material, let's look at it. This is eight months before you launched it.
Didn't you have a responsibility at that point to say, let's look into this and let's figure out what the best material is before we sell this? Shouldn't that have been what you did?
MS. KABBASH: Objection.
THE WITNESS: If Prof. Jacquetin would have come to us and said, well, look, Axel, this is -- there is a big issue. The erosion rate is too high. There are retraction. I think we should look for a better material. Then the things would have been different. But that is not what he was saying.

BY MR. SLATER:
Q. Does Prof. Jacquetin run your company?
A. No.
MS. KABBASH: Objection.
BY MR. SLATER:
Q. Sir, sir, Prof. Jacquetin told you clearly, not just here, but you know he told you multiple times, the shrinkage cannot be fixed with this mesh material. We need to find a different mesh material that won't have this shrinkage, because it's creating an unmet need. We can't ensure good sexual activity post-surgery, especially for young women, any woman but especially for young women who have a long life ahead of them. He told you that.
Don't you, as a company, have an obligation to study this and figure the answers out, is this the best mesh? Or maybe we don't sell it, because we can't stop this complication from occurring? Don't you have to look at those questions?
MS. KABBASH: Objection, compound, asked and answered, argumentative and mischaracterization.

MR. SLATER: I'll rephrase. I'll withdraw the question and ask it again.
BY MR. SLATER:
Q. This is eight months before the Prolift® was launched. You could have studied other available mesh materials. You could have commissioned a clinical study using different alternatives like Prolift® with Gynemesh® PS, Prolift® with Ultrapro®, Prolift® with another mesh material you thought might be good. You could have studied it for longer. You could have taken some time and tried to figure out what really is the best available mesh material, because there are serious problems with the Gynemesh® PS that we can't fix. We can't fix the shrinkage. So let's take a look and figure it out before we go to market. You could have done that. Right?
MS. KABBASH: Objection.
THE WITNESS: You could always have done everything. But, you know, at some point, where were we standing there? We're standing with clinical experience. The erosion rate was now fixed to a low level. There was some shrinkage, nothing massive. We have -- when I'm talking about Prof. Jacquetin, I'm not talking -- I'm talking about,

rather, on the TVM Group. So it's not the opinion of one single person, it's opinion of ten expert or nine or ten expert that were meeting on a regular basis. And none of them told us, you know, you should not go on the market. This is dangerous. This is not at all what we heard.
What we heard was, we are very happy. The technique is nice. The erosion rate is fine. We have some retraction. Most of the time it is not an issue. They never found -- they never found these exceptional cases you just mentioned prior to this question. So --
BY MR. SLATER:
Q. How do you know they never had a case like that? How do you know they didn't have patients where they couldn't cure the complications from retractions or exposures or erosions?
A. At least on July 16, 2004, I never heard about that and never mentioned that. You cannot find an e-mail I think where they would mentioned such.
Q. So those types of complications, the really serious ones like we've been discussing, they only started happening once the mesh was packaged as the Prolift® and began to be sold, and it was only

after the Prolift® was on the market that you started to see those types of complications?
MS. KABBASH: Objection.
THE WITNESS: Usually the exceptional --
BY MR. SLATER:
Q. Is that what happened?
MS. KABBASH: Objection.
THE WITNESS: -- the exceptional complication occur when you sell to a huge lot of people, you know. As soon as you are in a clinical trial, if something occur in 0.001 percent, if you have a study with 100 patients, very unlikely you will find this complication. It's a general principle in medicine. And we have seen that many time.
You know, with the slings, exceptional complication occurs. But they occur because they are used by hundred and hundred of thousands of patients. But what you're talking is an exceptional situation. It's very exceptional. So --
BY MR. SLATER:
Q. Well, as -- I'm sorry.
A. So maybe in a big country like the

US, you can collect some cases, but what is exceptional is not something that is detected by the clinical trials.

Q. Did you ever -- right now, here we are, November 15, 2012.

As you sit here now, did your company ever make an effort to identify how many women would suffer the very serious complications that would cause permanent impairment?

A. I don't know.

Q. Did you ever make an effort to quantify that?

A. I don't know.

Q. And let's look now -- well, let me ask you this.

You just testified earlier that Prof. Jacquetin and his group were very happy with their erosion rate that they had established with the TVM technique using Gynemesh® PS. Right?

A. That's what I read in this e-mail.

Q. Are you aware that their erosion rate at one year in the TVM study, if you counted all the exposures of mesh into the vagina that occurred as of one year, it was 20.7 percent of the women?

MS. KABBASH: Objection.

THE WITNESS: Yes, I am aware of that.

BY MR. SLATER:

Q. And it's your testimony to this jury that that's acceptable to you? That the top surgeons in the world, the very best, had a 20.7 percent erosion rate at one year, yes or no, that's acceptable to you?

A. What I observe --

Q. Is that acceptable to you?

A. Yes.

Q. Let me ask you this.

And you knew, you knew, that their erosion rate and their exposure rate would be better and lower than other surgeons who weren't as experienced and didn't have years of working in developing this procedure so you could foresee that likely the erosion and exposure rates out in the community when you marketed this on a widespread basis would be even higher than 20 percent. You knew that. Right?

MS. KABBASH: Objection.

THE WITNESS: This is not correct at all.

BY MR. SLATER:

Q. So you didn't anticipate that Prof. Jacquetin and his group would have a lower exposure rate than surgeons out in the community?

A. No.

MS. KABBASH: Objection.

THE WITNESS: This is not correct, because --

BY MR. SLATER:

Q. Fine. Your answer's no.

A. -- the study you're mentioning is not performed with the Prolift® system. It's performed with tools that were very difficult to handle, that were creating some tears in the tissue. And that's exactly the reason why we developed specific adduct tools, in order to improve the way this procedure was made to avoid the tear in the tissue. So the 20 percent rate is not reflecting the situation with the Prolift®.

On top of that, you are talking about a key expert. But, once again, a key expert that is starting a procedure is a beginner. He is not --

Q. Doctor, he's been doing the procedure since 2003 when they perfected their procedure, so-called perfected it. So he had been doing it for over a year.

A. Yeah.

Q. And he was the person who created the procedure.

Who other than him would be better than him at it?

A. You're right. But in the trial you're mentioning, is that a trial of Prof. Jacquetin or is that a trial of a group of surgeons?

Q. I'm asking about the TVM study that your company sponsored.

A. Yes, I'm talking about that. And in the TVM study, it's not a Jacquetin study. It's a study of a whole group of people who did not necessarily -- who were not necessarily performing the same procedure. All these eight people are there to learn the new procedure.

Q. Are you saying that --

A. So they were in the learning phase of a procedure. And despite being in the learning phase with bad instruments, they end up with 20 percent of erosion, which, again, is not a killer for the project, because 20 percent of a minor complication, that should not be viewed as a killer.

Q. So you're telling me that the TVM study that the French surgeons performed, they were

in their learning phase, they were using what you just called, and I'm quoting you, bad tools?

A. Inadequate tools.

Q. Bad tools, inadequate tools. Correct?

A. Yes.

Q. And is it your testimony that you cannot take the TVM studies that were sponsored by your company to study this TVM procedure with the Gynecare PS, you can't use those to project what would happen with the Prolift®?

MS. KABBASH: Objection, mischaracterization.

THE WITNESS: Well, I can't make a projection. If you give to these people better tools and more experience, it's very likely that the result will improve. And that's what happened after a while. You know, they were pioneer using tools that were very rudimentary. They were -- all of them, most of them, if not Prof. Jacquetin, most of them, including in the US and Europe, they were beginner, beginning, pioneer in a new procedure. So it's not big surprise that they got 20 percent of erosion rate. That's not very shocking for me.

BY MR. SLATER:

Q. So they were pioneers.

In essence, this was in the experimental phase?

MS. KABBASH: Objection.

THE WITNESS: This was a clinical trial in the early phase of the project. So it was a pioneering phase for sure.

BY MR. SLATER:

Q. Pioneering, would that be equivalent to experimental?

MS. KABBASH: Objection.

BY MR. SLATER:

Q. They were in the experimental phase?

A. They were in clinical research.

Q. Would you consider the TVM study to have been an experimental phase in the development of this procedure, the actual US and French TVM studies?

A. Well, I don't understand what you mean by experimental phase. It's very simple. It's a clinical trial to test a new procedure.

Q. When I say experimental, I'm saying there's not enough data to be able to give an expectation to a patient as to what the risks and benefits of the procedure would be, since it's in

such an early phase that it would be, quote/unquote, experimental.

Was that --

Is that a fair description of the TVM studies, the US and French?

A. Can you repeat that, because --

Q. Sure.

A. I tell you why we have a --

Q. I'll slow down.

A. Experimental and clinical trial means something different, so please, if you could say that in a --

Q. Would you -- well, rephrase.

Was the US and French TVM study experimental in the sense that if a patient were to ask, well, what should I expect my outcome to be, the surgeons would have to say, look, this is really at a phase where we can't give you a good expectation of what the risks are and the benefits. We know what we hope will happen, but we're still learning and we're still experimenting, so we're not able to give you expectations.

Would that be a fair statement for the TVM studies?

MS. KABBASH: Objection.

THE WITNESS: I'm not sure I understand, but, you know, for the patient, it was -- they were entering a clinical trial. In a clinical trial, you do not necessary carry a special risk, you know. They were operated by the best expert doing a new procedure. So that's something that happen in medicine every day.

BY MR. SLATER:

Q. Were those patients in the TVM study told that the doctors were in their learning phase using what you've termed as bad or inadequate tools and that they could expect an erosion rate potentially of 20 percent or more into their vagina of the mesh? Were they told those risks?

MS. KABBASH: Objection.

THE WITNESS: Well, I don't have the informed consent, you know, that they received and utilized, but I --

BY MR. SLATER:

Q. They should have been told that. Right?

MS. KABBASH: Objection.

THE WITNESS: I guess the surgeon did what they had to do.

BY MR. SLATER:

Q. Well, your company --
Since you're involved with the trial, your company actually had to pass on each of the informed consent forms. Right?
MS. KABBASH: Objection.
THE WITNESS: Probably.
BY MR. SLATER:
Q. So you would agree the consent forms should have disclosed to the patients that the physicians were in their early learning phase, that the tools were inadequate or bad tools, as you've described them, and that they could expect a rate of exposure of the mesh into their vagina of 20 percent or more?
MS. KABBASH: Objection.
THE WITNESS: Well, no. I cannot agree with such an exaggerated situation.
BY MR. SLATER:
Q. I'm using your words, sir.
MS. KABBASH: Objection.
THE WITNESS: Okay. Maybe my word were exaggerating then.
But, you know, they were using the tools they would have used normally first. So it's rudimentary tool with regard to the project, but

this was a tool they were using in their practice. So each surgeon took the tool they were used to use in their practice, so no new tool. And they were doing a procedure. So these people were used to do procedure with meshes. They were not complete beginner. So they were -- they change their technique. So, yes, for the patient, it is different than if there were using the technique they were routinely using.
BY MR. SLATER:
Q. Did each of the surgeons in the French and US study use different techniques to place the mesh as part of the studies, or did they all follow exactly the same procedure?
A. Well, you know, they try to follow the same procedure, of course.
Q. Was anything ever done to try to monitor to see if any of them were varying the procedure in any way?
A. No.
Q. I'm going to hand you a document I've marked as Exhibit 619. Well, somebody marked it, it might have been me, at a prior deposition.
And this is an e-mail chain from January 11, 2005 to January 13, 2005. So now we're

about two months before the Prolift® was launched. And if you could, turn to the second page of the e-mail.
On January 11, 2005, here the first e-mail of the chain, you wrote an e-mail to Ophelie Berthier regarding the Prolift® IFU. Correct?
A. Yes.
Q. And you knew what the IFU was. Right?
A. Yes.
Q. That would be the instructions for use that would be given to doctors so they would understand from Gynecare what are the risks, what are the warnings, what do I need to know, what's the most important information I need to know about the Prolift®. Right?
A. Yes.
Q. And you wrote in this e-mail, "Ophelie: I suggest to propose to add the following to the new version of the IFU:
"WARNING: Early clinical experience has shown that the use of a mesh through a vaginal approach can occasionally/uncommonly lead to complications such as vaginal erosion and retraction which can result in an anatomical distortion of the

vaginal cavity that can interfere with sexual intercourse. Clinical data suggest the risk of such a complication is increased in case of associated hysterectomy. This must be taken in consideration when the procedure is planned in a sexually active woman."
And then you close by saying, "Regards Axel." Correct?"
A. Correct.
Q. And then if we follow the e-mail chain up, we see Ophelie Berthier forwarding that proposed warning that you had written to be included in the IFU to Scott Ciarrocca, who was one of the project leaders on the project. Correct?
A. Yes.
Q. And the reason you wrote that e-mail and proposed that warning was obviously because you thought it would be a good thing to put it into the IFU. Correct?
MS. KABBASH: Objection.
THE WITNESS: That's not correct, because the reason for this e-mail is that Ophelie Berthier was working next door to me, asked me assistance, because the TVM Group has found in their early experience that hysterectomy was associated

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with a higher rate of erosion. So Jacquetin was recommending that we should put this information in the IFU. So Ophelie Berthier was in a hurry because the new IFU was about to be edited, asked me assistance and asked me, Axel, could you just reword the warning section in order to include this information about the associated hysterectomy. So that's what I did. I rewrote the warning and I added this associated hysterectomy information. But then my understanding of this is that it was not included in the new IFU.

BY MR. SLATER:

Q. You can actually see, if you go up to the next e-mails in the chain, if you go to the top of the first page of Exhibit 619, that what happened was it was decided by Scott Ciarrocca and Sean O'Bryan that since the IFUs had already been printed, they would put the warning in the next IFU. That's what it says here. Correct?

MS. KABBASH: Objection.

BY MR. SLATER:

Q. Correct?

A. Yes, but, again --

Q. That's what it says in the e-mail. Right?

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A. Again, what's important is the difference in between the existing IFU and what I wrote. And the difference for me is only about hysterectomy. So the information about hysterectomy was based on data that were not very strong data, and -- but we thought this still should not be -- should be told to the surgeon, because it could be useful. If, for example, they were hesitating to perform a hysterectomy or not to perform a hysterectomy, which is a big debate in this area, they might be inclined to not to do the hysterectomy, because the hysterectomy gave more erosion. So that's the purpose of this -- of all these e-mail chain.

And my understanding is that at some point, the people in Somerville said, well, it's too late, the IFU has been printed, but we offer a solution, and the solution is to put that in the prof ed, education material, the surgical technique. We'll introduce that as a warning or we'll inform the -- we will communicate this information by another way than by the IFU.

Q. Okay.

A. That's my understanding.

Q. Let's look at what the e-mail

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actually says when you wrote him -- when you wrote the e-mail and when Ophelie wrote it back in January of 2005. Let's look at the actual words that you folks used.

A. Yeah.

Q. In your e-mail you wrote to Ophelie Berthier and said, "I suggest to propose to add the following to the new version of the IFU."

So you're telling her in the e-mail I'm proposing this warning. Correct? That's what the e-mail says. Right?

A. Yes, yes.

Q. And then you write out a detailed warning. Correct?

A. Yes, yes. Because she was asking me to write an IFU that -- a warning that would include the hysterectomy issue. So I wrote it.

MR. SLATER: Move to strike from "because" forward.

BY MR. SLATER:

Q. So after you send this e-mail to Ophelie Berthier, she forwards it to Scott Ciarrocca. And right there at the top of the second page, she says, "Here is the adding sentence Axel is proposing to incorporate in the IFU."

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So you were proposing to add this language to the IFU. Correct?

MS. KABBASH: Objection.

BY MR. SLATER:

Q. That is what you were doing. Right?

A. No. I was rewriting the warning in the IFU. It does not mean that this was not already in the IFU. A lot of what I'm writing was obviously in the IFU. The only thing that was not in the IFU was the associated hysterectomy.

Q. Doctor, I know the IFU by heart. So let's not do that. Okay? It doesn't say anything in the IFU about vaginal anatomic distortion. Those words do not appear in the IFU. Correct?

A. Yeah, but, you know --

Q. Doctor, stick with my question.

A. I stick with you.

Q. Those words don't appear in the IFU. Right?

A. Of course not all the words appear in the IFU.

Q. Well, you know what? Let's stick with the words I actually asked you about, with all due respect.

Nowhere in the IFU does it say that a

woman can end up with vaginal erosion and retraction which can result in an anatomical distortion of the vaginal cavity that can interfere with sexual intercourse? It doesn't say that in the IFU. Right?

MS. KABBASH: Objection.

THE WITNESS: Well, the IFU --

BY MR. SLATER:

Q. Doctor, why are you saying "but"? With all due respect?

MS. KABBASH: Adam --

MR. SLATER: No, no, no.

MS. KABBASH: -- let him respond to your question.

MR. SLATER: No. Listen. This is what we're going to do.

BY MR. SLATER:

Q. You want to go back to France tomorrow, and you're asking me to finish by 3:00. So let's play on a field where you have a shot at it. Okay?

If I ask you a yes or no question, don't start the answer with "but" and go off to your talking point, with all due respect, because you're never going to get done, because I'm going to take

my deposition. Okay? That's what I'm here to do. So I don't care what they told you in the other room to not answer my questions directly. I don't appreciate it. Okay?

You're testifying in a trial right now. And you have an obligation to answer my questions directly. So if they want to ask you something later, they can ask you whatever they want when I get done with my deposition. They'll do it then. But if I ask you, is the words -- do those words appear, it's a simple yes or no. If they want to ask you later some other question, they can ask you later. You are never going to get done, with all due respect, if I can't get direct answers to incredibly simple questions.

I'm asking you if words that I'm reading appears in the e-mails, for example, I can't get an answer.

MR. SLATER: Counsel, I know what you're going to say. I don't care. I'm going to ask a new question and let's hope that we can move forward through this, because I will go all night if I have to and all day tomorrow.

So here we go.

MS. KABBASH: You will ask a new

question after I get done putting something on the record.

First --

MR. SLATER: I don't even want to hear it.

MS. KABBASH: I don't care if you want to hear it.

MR. SLATER: I don't want to hear it. I'm not getting responsive testimony. I'm not going to stand for it.

MS. KABBASH: First of all, please stop asking questions argumentatively and belligerently.

MR. SLATER: I'm not doing either one.

MS. KABBASH: Second --

MR. SLATER: And this is on video, you can hear my voice.

MS. KABBASH: -- of all, please stop pointing your finger aggressively at the witness and at me.

MR. SLATER: Oh stop.

MS. KABBASH: And, third of all, please stop threatening the witness with how long this deposition is going to take.

MR. SLATER: I am not threatening.

MS. KABBASH: His --

MR. SLATER: I'm trying to be courteous. And if I can't get direct answers, it's going to be impossible to finish.

MS. KABBASH: His obligation is to answer the questions truthfully and completely, not to answer them in the order of words in which you would like.

MR. SLATER: I don't understand that. I don't understand that.

MS. KABBASH: I'm sorry that you don't understand that.

MR. SLATER: If I ask him is today Thursday, and I get a "but" to answer the answer, but, you know, it's closer to Friday -- it's getting close to Friday, is that responsive?

MS. KABBASH: I am asking you to take it down a notch, Adam. Okay? I've put my objection on the record. Go ahead.

BY MR. SLATER:

Q. All right.

Dr. Arnaud, on January 11, 2005, you sent an e-mail to Ophelie Berthier, and you told her you were proposing the following warning be added to

the Prolift® IFU. Correct?
A. Correct.
Q. When you used those words, you meant what you were saying. Right?
A. Yes.
Q. And then she forwarded that warning and that language to Scott Ciarrocca. Correct?
A. Correct.
Q. And then later in the e-mail chain, you see Scott Ciarrocca and Sean O'Bryan pointing out that since they've already printed the Prolift® IFUs, they're not going to include it in this version, they'll include it in the next revision. Correct?
A. Correct.
- - -
(A discussion off the record occurred.)
- - -
BY MR. SLATER:
Q. I'm marking now as Exhibit 1261 e-mails from July of 2005.
- - -
(Deposition Exhibit No. Plaintiff's-1261, E-mail chain, top one

dated 14 Jul 2005, Bates stamped ETH.MESH.03911629 and ETH.MESH.03909830, was marked for identification.)
- - -
MR. SLATER: For the record, 1260 just got skipped.
BY MR. SLATER:
Q. Now, Exhibit 1261 starts off with an e-mail that was written by Dennis Miller, who was a doctor who worked with Ethicon. Correct? An outside doctor who acted as an investigator and a consultant. Correct?
A. Well, I suppose so, yes.
Q. And following these e-mails from him, Cheryl Bogardus forwarded that on to you and asked you if you could provide some references that Dennis Miller asked for that he wanted to use going forward. Right?
A. Yes. Right.
Q. And then you e-mailed back. And let's go about halfway through your e-mail of July 14, 2005.
In that e-mail, you say that you agree with some of the things that -- or you agree with Dennis Miller 200 percent, that Jan Deprest

from Belgium.
And who is that?
A. Jan Deprest, he's a gynecologist from Belgium, Leuven, Belgium, and he has a particularity to have a lab. And the specialization of this lab is to study meshes and biomaterial, but including meshes more specifically.
Q. You point out that "Jan Deprest from Belgium is an exceptional guy, probably the surgeon in the world that know the most about mesh biocompatibility and tolerance."
That's what you said. Right?
A. Yes.
Q. And then a little further down, you say, "I visited him recently with Gene Kammerer."
So you're pointing out that yourself and Gene Kammerer met with Jan Deprest. Correct?
A. Yes, yes.
Q. And you met with him "in order to define how we could start working closer to him. One of the underlying" ideas "we had with Gene is to have him screen for us various mesh prototypes in order to define which would be the best for reducing mesh shrinkage." Correct?
A. Yes.

Q. So, again, in July of 2005 here, you're continuing to try to find a way to reduce mesh shrinkage and particularly with the Prolift® as well. Correct?
A. Yes.
Q. I'm now going to give you an exhibit, actually, a pair of exhibits. One is Exhibit 222, which is really just to tell us what the next exhibit is, which is Exhibit 495.
And for the record, Exhibit 222 is an e-mail from Giselle Bonet, dated January 17, 2005. And it's with regard to the beta launch meeting to be held January 19th to the 21st. And it attaches an agenda which shows that on January 19, 2005 you would be presenting a presentation called "Graft or No Graft." Correct?
A. Yes, that's correct.
Q. And Exhibit 495 is that presentation that you gave during the beta launch, "Graft or No Graft." Correct?
A. Yes, yes.
Q. And the beta launch meeting was a meeting that was focused on the initial launch of the Prolift®, which was targeted to a selected small group of surgeons. Correct?

A. Yeah, yes. I think it's correct.
Q. And let's look at the "Graft or No Graft" presentation.
We have up on the screen now the cover of your PowerPoint that you gave January 19, 2005 at the beta launch meeting. Correct?
A. Correct.
Q. And let's turn now to the first page after the cover.
When you gave that presentation, the question one you put in there, right on the first page, "Surgery or Abstention."
That's the first question that would have to be asked. Right?
A. Absolutely.
Q. And then on the next page, you have a scale weighing the risks and the benefits.
And that's a question that any surgical decision has to ask is what are the risks and benefits of the options for this patient. Correct?
A. Cannot agree more than that with you.
Q. Let's go to the next page.
The next page, you have a Latin term at the top, it's pronounced primum non nocere?

A. Yes.
Q. What does it mean?
A. First of all, do not harm.
Q. First do no harm?
A. Do no harm, yes.
Q. And that's a principle that physicians are supposed to follow at all times. Correct?
A. It is correct.
Q. It's a principle that a company like Gynecare or Ethicon should follow as well. Correct?
A. If physicians follow it, the company should follow it.
Q. And under first do no harm, you say, "Pelvic organ prolapse is a functional disorder not a life threatening disease."
And you're saying that because you want to put it in perspective. Correct?
A. Correct.
MS. KABBASH: Objection.
BY MR. SLATER:
Q. And number one you say, "Abstention is always a possibility." Right?
A. Right.
Q. Abstention is always a possibility

meaning you don't need to have surgery because, again, it's a functional disorder, not a life-threatening disease. Correct?
A. Yes. You know, what I mean surgery is not -- you can always -- it's not life-threatening, so you're not going to die with this. So surgery is not mandatory. It's just your choice.
Q. And then you say number 2, under the heading of "Primum non nocere," first do not harm, you say, "Whatever the treatment, it must not create serious complications." Right?
A. Yes.
Q. And that was a principle that you certainly feel applies to surgeons. Correct?
A. Yes.
Q. And you certainly believe that with any system or procedure or product that Gynecare or Ethicon would market, that principle should hold true as well. Correct?
MS. KABBASH: Objection.
THE WITNESS: This is the absolute goal of a surgeon.
BY MR. SLATER:
Q. In marketing any procedure or any

device, certainly Gynecare and Ethicon, if they're going to offer it, they would not want to be offering something that's going to create serious complications. Correct?
MS. KABBASH: Objection.
THE WITNESS: Again, you know, any time you talk about surgery, you can have serious complication. Everything is a matter of how often does that happen. You know, this is the ultimate objective of a surgeon and should be the ultimate objective of a company.
Now, we are not in an ideal world. Even with the best procedure, the lightest procedure, the less dangerous procedure, you may end up with something wrong. That's, you know, the general situation in surgery.
So what I'm writing there is my philosophy, and I guess the philosophy of my company is, of course, in what we are doing, we are trying to do the best for the patients.
BY MR. SLATER:
Q. Did you know at that time when you gave this presentation that the use of the Prolift® could result in serious complications for patients, complications related to the Prolift® procedure and

the Prolift® instruments and the Prolift® mesh itself?

A. Forever, I've always known that Prolift® being a surgical procedure could lead in complication and, in the worst case, this could be bad complication. But that's not -- that's not specific to Prolift®.

MR. SLATER: Move to strike from "but" forward.

BY MR. SLATER:

Q. With regard to the Prolift®, and with regard to the procedure, the actual technique and method, the mesh itself and the instruments that your company sold for the unique use with the Prolift®, what were the serious complications you knew, as of the launch of the Prolift®, that could occur due to the Prolift® surgery?

A. There are two aspect in your question. There are complication we knew because they occurred, and there are complication we could anticipate. You know, for example --

Q. I just want a list, the best list you can give me.

A. No. I give you an example. You pass needles through the obturator foramen. So even in

the clinical trial, you have had no complication. But you know from a large experience in passing a needle in the foramen, in the obturator foramen, in the TVT-O®, that it could happen that maybe you can hurt the pudendal nerve. So I know that probably it is something that can happen. Is it going to happen? I don't know. But you know any time you operate someone, something might go wrong.

So your question, you know, was I aware of a potential complication? Yes, I was aware of complication that have already occurred, like erosion; but I could also imagine other complication, as I told you, including death, because there is an anesthesiology, so death is a potential complication.

So if I understood you correctly, I should have stop everything by saying, well, first primum non nocere. We know that it's a functional disease, we know that the patient can die from the anesthesia, so stop it, no operation, death, finish. This project is dead. And the surgeon should not operate these people.

The fact is that the surgeon operate people with prolapse and get sometimes bad result, whether they use a mesh or not a mesh. You know, if

you perform a colporrhaphy, you can end up with a death, you can end up with complication, so -- but that's not -- does not mean that the guy who made the colporrhaphy is not following this nice principle primum non nocere, but, of course, after a while you could say, oh, if I knew I would have had this complication, I should not have operated this lady. That's fine, but that's not practical.

MR. SLATER: Move to strike.

BY MR. SLATER:

Q. One of the things your company had to decide was, are we going to put the Prolift® systems on the market and sell it to be put into patients' bodies. You had to make your own independent assessment of whether or not you felt that the risks were outweighed by the benefits such that would you sell this. Right?

A. Yes, yes, absolutely.

Q. And when you did that, what was your understanding, at the time the product was first marketed, as to the Prolift®-specific complications, the serious complications, that could occur as a result of a woman having a Prolift® put in her body with the Prolift® technique, inclusive of the Prolift® mesh and the Prolift® instruments? What

were the serious complications that could result from that, if you're able to tell me?

A. Serious complication, I can give you a very long list of what could have happened. You know, any -- you pass a needle. So you pass a needle, not only one, you pass two, three, three passage. So any time you pass a needle, if you -- you can catch a vessel, you can catch a nerve, you can catch the bowel, the bladder, you know. There's plenty of risk. The issue -- the question is how to manage them. Is Prolift® a procedure that is sufficiently reproducible, sufficiently well described in order to make this complication remain exceptional?

MR. SLATER: Move to strike.

BY MR. SLATER:

Q. Can you go to the page that's titled "Hazards of the Use of Grafts for Vaginal POP Repair"?

- - -

(A discussion off the record occurred.)

- - -

THE WITNESS: I got it.

MS. KABBASH: Axel, next time you

have to put page numbers on your presentations.
THE WITNESS: Yes.
BY MR. SLATER:
Q. In the "Graft or No Graft" presentation you presented to the beta launch meeting on January 19, 2005, one of the slides says, "Hazards of the Use of Grafts for Vaginal" prolapse "Repair."
And the first hazard you listed is "Graft Infection." Correct?
A. Correct.
Q. And that was one of the risks that you knew at the time, that the mesh could become contaminated and lead to an infection. Correct?
A. Yes.
Q. The second hazard you listed is "Vaginal Erosion." Correct?
A. Yes.
Q. And then you list three ways that you question that it may occur, "infectious," "ischemic" or "mechanical." Correct?
A. That's what we already discussed.
Q. And the third hazard you listed is "Vaginal Retraction." Correct?
A. Yes.

Q. When you refer to vaginal retraction, what are you referring to? Are you talking about where the mesh retracts and causes an anatomic distortion of the vagina?
A. I'm talking about, you know, there is a dissection. We put a mesh. There is a wound healing, and the wound healing process might be excessive and lead to some kind of retraction, of local retraction.
Q. If you go forward about another ten pages, there's a heading that says, "Reasons to be Cautious about Biological Grafts."
Number 7. It's number 7.
A. This one?
Q. Yep.
A. Got it. Oh, yes.
Q. In your presentation, part of your presentation was with regard to biological grafts. Correct?
A. Yes.
Q. And with regard to those, you're saying to the people at the meeting, you need to be -- people need to be cautious about those, because there's a "Lack of Long-Term Outcome Data" Correct?

A. Correct.
Q. That's because you believe any time there's any sort of a graft, whether it's synthetic, biologic or anything, if there's a lack of long-term outcome data, you need to be cautious about using that. Correct?
MS. KABBASH: Objection.
THE WITNESS: Well, this is different. You know, we are talking about a biological graft. So biological graft are very new product. You know, synthetic grafts have been used since the 1960s, where biologic graft are just brand new, maybe a couple of years. So I'm just emphasizing in this slide that with biological graft, there is a lack of long-term data, you know. Nobody knows exactly what it's going to be in the long term. Why, we have much more long-term data with meshes. Polypropylene meshes have been used since the 1960s. And the first implantation was in the 1940s, so that's what I mean.
BY MR. SLATER:
Q. You had no long-term data for the Prolift® itself when it was launched. Correct?
MS. KABBASH: Objection.
THE WITNESS: Well, the Prolift® is a

procedure, you know. We had long-term data about polypropylene mesh. It has been used forever.
BY MR. SLATER:
Q. Is the answer to my question yes, you had no long-term data regarding the Prolift® when you launched it?
MS. KABBASH: Objection.
THE WITNESS: No. We had no long-term data, because, of course, we launched it, so how can you have long-term data if you launch a product? We had long-term data about the material used in the product.
MR. SLATER: Move to strike from "because" forward.
BY MR. SLATER:
Q. I'm now going to show you --
I'll hand you an exhibit I marked as 485 at a prior deposition. And this is a document titled "Next Generation Mesh Discussion, March 10, 2005."
And you attended this meeting along with a few other people, including Gene Kammerer. Correct?
A. Yes. I just try to remember where it was, but yes, probably. If my name is there,

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there's no doubt I was there.
Q. And right in number 1, under "Current Priorities," it says, "For competitive reasons, the most immediate need is to complete a Technical Assessment of Ultra-Pro and compare with GYNEMESH PS to determine if Ultra-Pro could be an alternative or additional material suitable for Pelvic Floor Surgery."
Do you see that?
A. Yes.
Q. When they talk about competitive reasons, they're talking about competition with other manufacturers. Correct?
A. Sorry?
Q. When you talk about competitive reasons, that signifies competition with other manufacturers. Correct?
A. Yes.
Q. And it says, "The most immediate need is to complete a Technical Assessment of Ultra-Pro" to "compare" that "with GYNEMESH PS" to see "if" the "Ultra-Pro could be an alternative or additional material" as compared to Gynemesh® PS. Correct?
A. Correct.
Q. This is the subject that had been

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discussed going back into 2004 by Gene Kammerer. Correct?
A. Yes. It does not change, you know. Same discussion was going over and over.
Q. I'm now going to show you a document we've marked as Exhibit 1187.
Exhibit 1187 is a document titled "Use of ULTRAPRO Mesh for Pelvic Organ Prolapse.. Repair through a Vaginal Approach." And it's authored by yourself and Gene Kammerer May 13, 2005. Correct? Correct?
A. Sorry, sorry. Yes, correct.
Q. No problem.
Let's look at the beginning under "Background."
In the fourth line or fifth line, actually, you point out that "Mesh exposure is rather common."
Do you see that?
A. Yes.
Q. So to represent to patients or physicians that mesh exposure was rare or that there was only a slight risk of mesh exposure would be incorrect. Right?
MS. KABBASH: Objection.

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THE WITNESS: To say that to who?
BY MR. SLATER:
Q. To say to doctors or to patients that mesh exposure, there's only a slight risk, would be inaccurate, because as you state here, it's rather common. Correct?
MS. KABBASH: Objection.
THE WITNESS: Well, if I would talk to a doctor and to a patient, I would make a distinction.
BY MR. SLATER:
Q. Well, it would be completely misleading to say to a patient, for example, in a patient brochure for the Prolift® that there's only a slight risk of mesh exposure since, as you state here, it is rather common. Correct?
MS. KABBASH: Objection.
THE WITNESS: Well, I don't feel that is correct. Because, you know, it's a matter of perspective. If you talk to a patient, if you consider that the erosion is going to occur in 10 percent of the case, on a patient perspective, you mean that in nine case out of ten you won't have the erosion. So it's not very common. It's rare.
If you speak to a surgeon who operate

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500 cases a year and he got 10 percent of erosion, he's going to get 50 such women coming back to his office, saying, well, look, Doctor, I have a problem with the erosion. So in a surgeon's perspective, it's not uncommon, it's something that occur, if you see what I mean.
BY MR. SLATER:
Q. You said in this document on May 13, 2005, two months after the Prolift® was put on the market, that mesh exposure is rather common. Right?
A. Yeah, it's rather common. I'm not saying it's common, it's very common, it's rather common. It's not something very rare. And, you know, we are always talking about the same thing. We are talking about something in the range of 5 to 15 percent. So how can I qualify that? Not -- isn't it true that this is rather common, 5 to 15 percent? I think it's the good wording.
Q. In your wording, rather common doesn't mean slight. Right?
MS. KABBASH: Objection.
THE WITNESS: Slight? I have a problem with the English. Slight, what does that --
BY MR. SLATER:
Q. Slight, very small.

A. Very small.
MS. KABBASH: Objection.
THE WITNESS: No. Rather common means that, you know, it can occur on a regular basis. It's not something that you see once a year.
BY MR. SLATER:
Q. A little further down you say, "Mesh retraction," which you say in quotes, ("'shrinkage') is a more uncommon complication but it is considered more serious. It can cause a vaginal anatomic distortion, which may eventually have a negative impact on sexual life. Its treatment is difficult."
That's what you wrote in this report. Correct?
A. Yes.
Q. And you knew at that point that the treatment of mesh retraction, also known as shrinkage, is difficult. Right?
A. Yeah, of course. You know, I don't know, but I suspect it was not easy. You know, as a surgeon, I imagine if you put a mesh anywhere in the body, if you want to remove it, it's difficult for just one reason. It's because the mesh is, by essence and by design, a matter that is incorporated and not encapsulated. If it was encapsulated, it

would be very easy. You just take a forceps and take it off. If it is incorporated, by definition, the excision will be more difficult, because there is no dissection plan.
Q. It can be a very damaging surgery when you have to try to remove, or when the surgeon has to try to remove, retracted or shrunken mesh that is causing complications. That can cause a lot of damage to the patient, just removing the part of the mesh. Right?
MS. KABBASH: Objection.
THE WITNESS: Of course. But the purpose of putting a mesh in the body is not to remove it. It's to cure a disease. If for any reason you are to remove part of it, it can be more or less difficult, depending where is the part that you need to remove. You know, if it's very superficial, it may be very easy. If it is in the depths of the obturator foramen, then it might be difficult. I don't know. But I just as a surgeon can say, well, it could be easy, but in sometime it will be difficult. And I can imagine difficult situation.
BY MR. SLATER:
Q. Did you ever make an effort to

specifically speak to surgeons who were experienced in removing Prolift® mesh when women had complications to try to learn from them the difficulties they faced in actually removing the mesh? Did you actually specifically look into that issue at any time?
A. We did not specifically do that, because, you know, it's something --
Q. I didn't ask you why. I just asked if you did it.
You said you didn't. Right?
A. We didn't.
Q. I'm going to show you an exhibit that's been marked at a prior deposition.
I show you an exhibit that was marked at a prior deposition, Exhibit 287. And what that is is a photograph of mesh that was removed from a woman at the Mayo Clinic in Rochester, Minnesota, a woman who was having complications. And that's mesh that had actually been removed from her body. And you can see the mesh with the tissue and the blood and the fibrosis, everything right on it.
You see that. Right?
A. Yes.
Q. When the Prolift® was launched, did

you understand that there were women who would have complications that would cause surgery that would be invasive enough that something like that would have to be cut out of their body? Did you understand that at the time of launch?
MS. KABBASH: Objection.
THE WITNESS: You know, we have already discussed that, but this, for me, you know, as a surgeon, is nothing very, very rare, you know. It's a piece of mesh that has been resected. It could be something that occur in urinary repair. And any time you use a mesh, you can end up with a complication that oblige you to remove part of the mesh. So this is not something -- it's regrettable but not something that really is extremely shocking for me.
BY MR. SLATER:
Q. So you knew at the time of the launch of the Prolift® that this would be the result of surgery for women, some women, who would have complications due to the Prolift®. That was known at the time the product was launched by you. Correct?
MS. KABBASH: Objection.
THE WITNESS: At the time we launched

the Prolift®, we knew that implanting a mesh in the human body, whether you do it in the inguinal area, in the abdominal wall, in the vaginal wall, may result in the need to remove it.

So your question, I can say, yes, we knew, because it's obvious that when you implant something, you might have, if something -- if something goes wrong, to excise it.

BY MR. SLATER:

Q. You knew that in order to remove mesh to this extent, that would take, in many cases, a great deal of surgical skill by the surgeon who would have to now try to remove part of the mesh. Correct?

A. Correct.

Q. And it would, therefore, be important to tell the surgeons who were going to consider using this on their patients that they would need to be familiar with how to treat these complications and how to do this type of surgery. Correct? You want to tell them. Right?

A. No, no, this is not correct for me, because, you know, surgeon are not children. You know, they know -- when you are a responsible surgeon, when you implant something in the body, you

cannot tell me that a normal surgeon do not ask himself how he's going to remove it if something goes wrong. This is absolutely basic, you know, ethical responsibility of any surgeon. So no surgeon is relying on Ethicon to know how to remove the Prolift® if it does not go smoothly. You know, I cannot agree with you on that.

Q. Are you --

Is it your viewpoint that any surgeon who would be able to put a Prolift® in would be proficient enough to remove mesh such as this?

A. Well, again, if you don't feel you are competent enough to assume both the operation and the consequence of the operation, then you should not carry it.

Q. Did your company ever explain, with regard to the Prolift®, what it would take and what could be the difficulties in actually removing Prolift® mesh from a woman's body if necessary, part of the mesh, revising part of the mesh, for example, like this, did your company, in a copy reviewed material, something official from the company, ever explain that?

MS. KABBASH: Objection.

THE WITNESS: Ever explain, you mean

how it -- how difficult it would be?

BY MR. SLATER:

Q. What you would actually be -- need to do in order to safely and effectively, if possible, remove mesh like this? Did your company ever in an official document explain that?

A. No. Because it is impossible to explain what kind -- you know, a complication might occur anywhere. So how can a company says -- describe the way you should remove this part or this part or this part. It's just impossible. It is just basic surgery.

If you have a complication in the obturator foramen, well, you're a surgeon. You need to go there. And it is not a company is going to tell you how to remove the mesh. You know, I cannot agree with you, because the surgeon, if he use it, he put it in place, he should know how to do without complication. That's the basis of surgery. Like a guy who pilot a plane, he should be able to take care of the plane whatever the weather condition are. You know, if the condition are bad, you cannot say, oh, the manufacturer of the plane did not tell me that the -- what to do when there is a storm. That's I think a fair comparison.

You know, if I'm a surgeon, it is my responsibility to put this in the body, but also my responsibility to know how to remove it, or at least then if I don't know, I can always ask for assistance by a senior surgeon, by an expert. But, you know, I don't think it would come to the mind of a surgeon facing a case where he need to remove the mesh in a very difficult area to ask Ethicon how to do it.

Q. Well, Ethicon never even tried to figure out whether there was any suggestions that could be given to surgeons to help them to safely and effectively remove Prolift® mesh. That's something Ethicon never made an effort to do. Correct?

MS. KABBASH: Objection.

THE WITNESS: Well, I don't think we ever did that, you know, because, you know, we sell suture. We don't put in the IFU how to remove a suture if there is a complication, because this is just basic principle of surgery.

MR. SLATER: Move to strike from "because" forward.

BY MR. SLATER:

Q. The removal of Prolift® mesh when a

woman has complications can go way beyond basic surgery or even sophisticated surgery can become incredibly complex. Right?

A. Right.

Q. Now, looking at Exhibit 1187 again, the one in front of you, you have a line towards the bottom of the first page, under "Physical Comparison to Gynemesh PS," "In summary our conclusions are that placing the UltraPro within the pelvic floor as a direct substitution for the Gynemesh PS is very reasonable." Correct?

MS. KABBASH: You know what, Adam? I'm sorry, I lost you. Can you tell me where you are again? Sorry.

BY MR. SLATER:

Q. In Exhibit 1187, your May 13, 2005 report on the use of Ultrapro® mesh for pelvic organ prolapse repair through a vaginal approach, you say, in the bottom of the first page, "In summary our conclusions are that placing the UltraPro within the pelvic floor as a direct substitution for the Gynemesh PS is very reasonable."

That's the conclusion you drew in this document. Correct?

A. Yes.

MR. SLATER: Go off the video.

THE VIDEOGRAPHER: The time is now 5:01. We are going off the record.

- - -

(A recess was taken from 5:01 p.m. to 5:15 p.m.)

- - -

THE VIDEOGRAPHER: The time is now 5:15. We are back on the record.

- - -

(Deposition Exhibit No. Plaintiff's-1262, E-mail chain, top one dated 25 May 2005, Bates stamped ETH.MESH.03911617 and ETH.MESH.03911618, was marked for identification.)

- - -

BY MR. SLATER:

Q. I've given you Exhibit 1262, which is two e-mails in May of 2005. The first e-mail Cheryl Bogardus wrote to you May 23, 2005.

Who is she?

A. US marketing person.

Q. And she asked you for some information regarding the history of the adoption of mesh in the hernia market to see if it would help

her to be able to project how many physicians would start to use mesh for vaginal repair of prolapse. Correct?

A. Yes.

Q. And you say in your e-mail back to her, "We must be careful in comparing prolapse and hernia repair."

That's right up at the top. Right?

A. Yes.

Q. You say that you see more of a similarity between hernia repair and the adoption of mesh for that as compared to the use of mesh for stress urinary incontinence.

That's what you say. Correct?

A. Yes, yes.

Q. Then we go down to the bottom, where it says, "Prolapse repair." You say at the first bullet point, there's a little asterisk, "The procedure which we bring is well described, it makes sense but it is not as easy to reproduce and to perform as the TVT or the Lichtenstein," which was a hernia procedure. Correct?

A. Yes.

Q. And then in the next bullet point, you say, "With the procedure," talking about the TVM

procedure, "it is very likely that the recurrence rate will decrease but there is a price to pay for that which is the possibility of mesh-related complications, such as mesh exposure and possible dyspareunias; neither Lichtenstein nor TVT were associated with mesh-related complications."

That's what you state. Correct?

A. Yes.

Q. So you're basically differentiating and saying that with the TVM procedure and the use of mesh to treat prolapse through the vagina, there are differences that make it less comparable to the use of mesh for hernia or for stress incontinence. Correct?

MS. KABBASH: Objection.

THE WITNESS: Yes.

BY MR. SLATER:

Q. Then on the next page, going over in terms of projecting how many surgeons would adopt the use of mesh for the treatment of prolapse through the vagina, you basically said that she should stay conservative, and she had projected ultimately over the next ten years, 36 percent of the repairs being the use of mesh through the vagina. And you basically say, you know, based on

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what I've just analyzed for you, you think that's a reasonable projection over the next ten years, the 36 percent. Correct?

A. Correct, yes.

Q. And that's in May of 2005. Correct?

A. Yes.

Q. Now I'm going show you a document we've marked as Exhibit 439. And this is a couple e-mails in November of 2005. And on the second page is your e-mail of November 23, 2005 to Giselle Bonet regarding, "Subject: PROLIFT improvements," Dr. Eberhard from Switzerland.

And you talk about the fact that he's someone you had an interesting meeting with, he's "a very good surgeon with a large experience with both" the "Perigee and" the "Anterior Prolift," and you point you out he had performed over 70 Prolifts®. Correct?

A. Yes, yes.

Q. And you point out in fact that he's what you call a good friend of Gynecare. Right?

A. Yes.

Q. And you say the reason why you visited him relates to suggestions he wanted to make regarding Prolift® improvement here in November of

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2005. Correct?

A. Yes.

Q. A little further down, you know, he talks a little about his preferences according to what you relayed here. And a little further down there's a sentence that says, "I also tried to explain that our device is designed to be safe even in the less skilled hands."

Do you see that, about halfway through?

A. Yes, yes.

Q. And that's one of the design goals of the Prolift®, it was intended that it would be used by less skilled surgeons, not just the most highly skilled?

MS. KABBASH: Objection.

THE WITNESS: Yes. Of course, we were not interested in providing a device for the ten more experienced surgeon in the world. We would like to have a broader market.

BY MR. SLATER:

Q. He points out to you in point 2, you're relating obviously what he said, that he believed the guide is too sharp. And you describe that. Correct?

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A. Yes, correct.

Q. You say, "This is unnecessary," according to Prof. Eberhard, and it "presents a risk for the vessel or bowel perforation," and he had suggested a blunter guide. Correct?

A. Yes, yes.

Q. Also, Prof. Eberhard suggested "A plastic sheath (as in" the "TVT) would protect the straps during the procedure." Right?

A. Yes.

Q. He also, one of his criticisms was that "The curvature of the guide is not ideal in particular for the anterior superficial passage." Correct?

A. Yes.

Q. And then he pointed out in number 5 -- well, rephrase.

In this e-mail of November 23, 2005, when you're relating Jacob Eberhard, Prof. Jacob Eberhard's criticisms of the Prolift®, you listed number 5. You say, "He believes that, after retrieval of the cannula, the straps take a rope-like shape which is not optimal in his opinion."

Do you see that?

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A. Yes, yes.

Q. And that's referring to when the cannula is actually pulled back off of the mesh, it actually looks like it's roped and actually is a rope-like shape. Correct?

A. Correct.

Q. Next I'm going to show you an exhibit I've marked as Exhibit 807. This is January 12, 2006, minutes of a telephone conference. And I can tell you, I'm simply going to ask you just two or three questions, so I think you'll be okay without having to read through the whole document.

At the very beginning, with regard to TVM, David Robinson "reported on his and" Cyrus Guidry's "review of the French data received from PJ," and that would be Peter Jones, according to the people who attended this meeting. Correct?

A. Probably, yes.

Q. And it says, "Failure rate 18.6%. US study failure rate appears to be 13.3% at this stage."

Do you see that?

A. Yes, yes.

Q. And when they're talking about failure rate, they're talking about anatomic

recurrence of prolapse. Correct?
A. Yes, yes.
Q. And it says here, David Robinson's "opinion is that these rates are presentable; could be better, but not a disaster."
Do you see that?
A. Yes.
Q. Certainly that's not a ringing endorsement of the efficacy of the Prolift®, that the failure rates in the two studies were 18.6 percent, 13.3 percent, and one of the medical directors in Ethicon Women's Health & Urology was saying the rates could be better, but they're not a disaster. Right?
MS. KABBASH: Objection.
THE WITNESS: Right. That's what is written.
BY MR. SLATER:
Q. And then further down, there's a heading, "Prolift." "Agreed that it is still to continue unaffected by TVM output."
Do you see that?
A. I see it, but I'm not sure I understand what it mean, agreed --
Okay.

Q. And what that's referring to is, despite the disappointing data coming from the TVM study, it was agreed by this group to continue to market the Prolift®. Correct?
MS. KABBASH: Objection.
THE WITNESS: Yes.
BY MR. SLATER:
Q. Let me give you what we've marked as Exhibit 808. And this is a chain of e-mails in which you are copied on some of them, starting with the e-mail at the bottom of the first page. And I'm going to go actually deeper into the chain, to an earlier e-mail. It's actually the first one in the chain, which is at the end, from Bob Roda to Peter Meier and several other people. And it's dated January 24, 2006.
Who is Bob Roda?
A. Bob Roda is a marketing person from the US.
Q. He points out in this e-mail, "Peter" -- and he's writing to Peter Meier.
Who's Peter Meier?
A. Peter Meier is -- he's a medical doctor that works in the R&D for Gynecare in Europe.
Q. Is he somebody that you've worked

with in the past?
A. Yes.
Q. Is he somebody who you respect?
A. Yes.
Q. And here Bob Roda says to Peter Meier, and obviously copies a few other people, the subject is "TVM discussions."
"Peter, I am coming back from the TVM meeting in Paris and wanted to reach out to you regarding a few ideas."
Do you see that?
A. Yes, yes.
Q. Do you remember a meeting that took place in Paris in January 2006 to talk about issues with the Prolift®?
MS. KABBASH: Objection.
THE WITNESS: I don't. I had so many meeting, but --
BY MR. SLATER:
Q. Do you recall that in January 2006, there was concern within the company, based not only on the results of the TVM study, but also on the information you were getting back from surgeons and from the adverse event reporting, there were concerns that the Prolift® needed to be modified or

something needed to be done if it was going to stay on the market?
MS. KABBASH: Objection.
THE WITNESS: Well, I don't recall that. I don't think there was anything very new, you know. We were aware of erosion, of contraction, and the discussion was ongoing, how to improve -- improve the situation.
BY MR. SLATER:
Q. I'm going to put up a part of this e-mail on the screen. And this is the first paragraph. It says, "Peter, I am coming back from the TVM meeting in Paris and wanted to reach out to you regarding a few ideas. The group is strongly looking forward to the potential for new materials for the Prolift product."
And when they talk about "the group," that's the TVM Group. Correct?
A. Yes.
Q. And it says, "Their main concern is the" belief "that the Prolene Soft material" -- and the Prolene® Soft material is the material in the Prolift®. Correct?
A. Correct.
Q. "Their main concern is the" belief

"that the Prolene Soft material over time contracts. Thus creating the potential for failures and/or erosions. What they would like to see is what materials that we might be able to create that would provide the scaffolding for the repair without the limitations they feel Prolene soft has."

Do you see that?

A. Yes.

Q. And this is the concern that the TVM Group and Prof. Jacquetin in particular were expressing going back to May of 2004. I showed you those materials earlier. Correct?

A. Yes.

Q. So the same discussion is still going on, can we find another material that will reduce these complications. That conversation is still going. Right?

A. Yes, yes.

Q. I'm now going to show you a document we've marked as 1263.

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(Deposition Exhibit No. Plaintiff's-1263, E-mail chain, top one dated 25 Oct 2006, Bates stamped ETH.MESH.03915722 through

ETH.MESH.03915725, was marked for identification.)

- - -

BY MR. SLATER:

Q. This is an e-mail from Ophelie Berthier to you, at least that's at the top of the first page, forwarding you the first draft of the clinical strategy for Project Lightning.

Do you see that?

A. Yes.

Q. And Project Lightning was the code name that your company came up with for the project that ultimately resulted in the replacement of the Gynemesh® PS mesh material with Ultrapro®, which was marketed as the Prolift+M®. Correct?

A. Yes.

Q. And this is the concept that had been discussed going back to 2004 in some e-mails that we've seen. Correct?

A. Yes, yes.

Q. And in this clinical strategy, if we look, there is a discussion of the fact that the mesh, through the TVM technique, according to this strategy says, "It significantly reduces recurrences compared to traditional POP repairs," but "it can

lead to other complications such as mesh exposure and mesh retraction."

Do you see that?

A. Yes.

Q. And what it says here is, "Mesh exposure is a common complication which can be managed by excision and closure." Correct? That's what it says here?

A. Yes, yes.

Q. So, again, we see your company internally recognizing that mesh exposure is common.

Do you see that?

A. Yeah. We've already discussed that. You know, instead of playing on words, common, rather common, more common, very common, the company knew that the rate of erosion was something around 10 percent, so...

Q. The next thing this document says, "Mesh retraction ('shrinkage') is less common but it is considered more serious. It can cause vaginal anatomic distortion, which may eventually have a negative impact on sexual function. Its treatment is difficult. Additionally, the scar plate that forms with in-growth of tissue into the mesh can cause stiffness of the vagina that further impacts

sexual function in a negative manner."

Do you see that?

A. Yes.

Q. And it was understood that with the Prolift®, this was a problem that your company was attempting to address and had been attempting to address for two years. Right?

MS. KABBASH: Objection.

THE WITNESS: Yes. It has been attempting to address it since the beginning of the project, because this was known before, before we even start the project. Any time you operate someone through the vagina, even more if you put a mesh inside, you could end up with excessive scarring retroaction. In a sexually active woman, it could have no impact, but it could also have some kind of impact. There is nothing new in this e-mail, you know, with regard to what we have already discussed.

BY MR. SLATER:

Q. Doctor, when you say there's nothing new, you're not saying just because it's understood that there are certain complications with regard to, for example, the Prolift® that was developed, that that makes it acceptable to you, just because the

complications are known to occur. Right?
MS. KABBASH: Objection.
BY MR. SLATER:
Q. Reask the question?
A. Yes, please.
Q. Sure.
When you say, well, the complication was known, you're not saying just because it's known that a complication can occur, that makes it acceptable. Right?
A. A complication can be acceptable, can be accepted in surgery. Again, I take a comparison. If you open the abdomen, you end up with 15 percent of incisional hernia. This is a complication that occur in 15 percent of the case. It's a serious complication. Nevertheless, it is accepted when a surgeon opens the abdomen everywhere in the world every day.
So, you know, I think there is a misunderstanding between us, but a complication does not -- the word "complication" does not necessarily mean it is very serious issue. It can be a complication that is accepted because it is tolerable, because when you put it in the benefit/risk balance, it does not bring the balance

in the wrong position.
MR. SLATER: Move to strike the discussion of abdominal surgery.
BY MR. SLATER:
Q. With regard to the Prolift®, your company had to do a risk/benefit analysis and decide whether or not, from your company's perspective, the complications were acceptable before you would put it on the market and represent to the world it's a safe product. Right?
MS. KABBASH: Objection.
THE WITNESS: Yes. Probably.
BY MR. SLATER:
Q. And in doing that, and in making that decision to say we're going to sell the Prolift®, it was done understanding that mesh exposure was a common complication, and mesh retraction, which was less common than exposure, was more serious, it could cause vaginal anatomic distortion, which could have a negative impact on sexual function, and that the treatment of that complication is difficult.
That was all known. Correct?
A. Yes, that was all known.
Q. It was also known, as stated here, that, "The scar plate that forms with in-growth of

tissue into the mesh can cause stiffness of the vagina that further impacts sexual function in a negative manner."
That was known. Right?
A. Yes.
Q. And then it says here, "In an effort to minimize these complications, the use of a lighter-weight alternative mesh for" pelvic organ prolapse "repair is being explored. This mesh would serve to replace the Gynecare Gynemesh PS used within the Gynecare Prolift Pelvic Floor Repair system." Right?
A. Yes.
Q. That was the purpose of Project Lightning and ultimately resulted in the Prolift+M®. Correct?
A. Yes.
Q. And this was something that was being discussed in your company a year or more before the Prolift® even was put on the market. Right?
A. Yes. That was discussed even before we put it on the market.
Q. If we look now at Exhibit 1157.
I'm just going to take you -- rephrase.

Exhibit 1157, which I put in front of you, at the top of the first page is an e-mail from Gene Kammerer dated February 13, 2006. And he wrote it to you and some other people regarding "TVM discussions," these discussions that had taken place in Paris. And he says, "This would be an excellent opportunity to gather some voice of customer for" next generation "mesh, and to resurrect the project."
And at the bottom of that e-mail, towards the bottom, there's a paragraph that says -- we're going to put it up on the screen.
The paragraph says, "I met with both Dr. Cosson and Prof. Jacquetin at the Paris meeting in 2004. They expressed and interest in a new mesh to control and reduce scar contraction. This led us, Axel and I to investigate the" Ultrapro® versus Prolene® Soft "conversion. The results of the investigation showed us that it could be done and we could possibly get an enhanced product. The team wanted to move forward, but then everyone got re-assigned, and so the project kind of went into limbo."
And that is what happened. Correct?
MS. KABBASH: Objection.

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THE WITNESS: I don't know if the project went into limbo, because at the end of the day, it finally came on the market.
BY MR. SLATER:
Q. Well, the project is now just starting to again be discussed two years later. Right?
MS. KABBASH: Objection.
THE WITNESS: Yes.
BY MR. SLATER:
Q. And that project is a follow-on to discussions that took place with Prof. Jacquetin and Cosson in 2004, where they had expressed an interest in a new mesh to control and reduce scar contraction. Right?
MS. KABBASH: Objection.
THE WITNESS: Yes, they expressed interest.
MS. KABBASH: I think we probably want to stop in the next couple minutes, Adam.
MR. SLATER: I have about three more documents, four more documents, so why don't we do that.
MS. KABBASH: Well, let's see how long it goes. I don't want to take too much longer.

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MS. SCALERA: Let's start and see --
MR. SLATER: I don't care about the time.
MS. SCALERA: Let's not go past 20 minutes.
MR. SLATER: Oh, we'll be done in 20 minutes.
MS. KABBASH: Are you okay for another 20 minutes?
THE WITNESS: Yes, yes.
MR. SLATER: He wants to keep going. I would if I was you. That's smart, rather than going nuts tomorrow afternoon.
THE WITNESS: Yes. I'm warm now, so...
MS. KABBASH: As long as you're okay.
- - -
(Deposition Exhibit No. Plaintiff's-1264, E-mail chain, top one dated 10 Nov 2006, Bates stamped ETH.MESH.03915831 and ETH.MESH.03915832, was marked for identification.)
- - -
BY MR. SLATER:
Q. Exhibit 1264 at the top is an e-mail

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from Ophelie Berthier to you dated November 10, 2006. And she just says, for your information. She's forwarding you another e-mail. Right? Do you see that?
A. I think so.
Q. The e-mail she forwarded you had been written by Allison London Brown, marketing director -- worldwide marketing director from Ethicon Women's Health & Urology. Right?
A. Right.
Q. And I want to draw your attention to her 2007 priorities. One of the things she says is, "Need clinical immediately on UltraPRO - prove concept of less dense mesh." And then she says -- Do you see that?
A. Yes.
Q. So she's looking to get clinical backup as soon as possible to support the concept of Ultrapro®. Correct?
A. Yes.
Q. And then she says, "PROLIFT data - either internal or external - needed for continued market development and acceptance."
So she's looking for data to be developed and provided to help to develop the

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marketing to give to surgeons to try to persuade them to use the Prolift®. Right?
MS. KABBASH: Objection.
THE WITNESS: Well, to develop the acceptance of the product, of the procedure, because -- it was not obvious, you know. It's a big move. From colporrhaphy to this procedure is a big move. So it's normal that we have to make effort to -- if we want to be successful with this procedure.
BY MR. SLATER:
Q. And this is not at the point of launch, of course. This is a year -- more than a year-and-a-half after the product had been launched already. Right? After the Prolift® procedure had been launched?
A. Yes.
Q. And then the next thing she says, let me ask you about that. She says, "We will build market awareness and push" -- excuse me, let me start over.
In this e-mail where the subject is "2007 Priorities for" pelvic floor repair, at the end of the e-mail, she says, "We will build market awareness and push education on the 'Mesh is not

Bad' message throughout the year with efforts around PFA and continue to drive sales of PROLIFT and GYNEMESH PS."

Do you see that?

A. Where is PFA?

MS. KABBASH: This line.

THE WITNESS: Yes.

BY MR. SLATER:

Q. So part of the marketing strategy for 2007 was to get out a message to doctors that mesh is not bad. Right?

MS. KABBASH: Objection.

THE WITNESS: Right.

BY MR. SLATER:

Q. I am going to give you a document -- I'm going to mark it, because I don't have marked copies, as Exhibit 1265. And I'll just state for the record this is the same document that was previously marked as Exhibit 1099.

- - -

(Deposition Exhibit No. Plaintiff's-1265, E-mail chain, top one dated 15 Nov 2006, Bates stamped ETH.MESH.03160750 through ETH.MESH.03160752, was marked for

identification.)

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BY MR. SLATER:

Q. And what I'd like to do is draw your attention to the second page where you wrote an e-mail on November 13, 2006. And the subject of your e-mail is "Pelvic Floor/Mesh Strategy."

Do you see that, page 2?

A. Yes.

Q. You point out in the first paragraph under "Lightning," which, again, was the product that led to the Prolift+M®. Correct?

A. Sorry?

Q. Lightning was the project that led to the Prolift+M®. Correct?

A. Yes.

Q. You say in that paragraph in part, second sentence, "We set up a meeting with some experts, including" Jan "Deprest and we asked them how we could improve the Prolift mesh."

Do you see that?

A. Yes.

Q. And Jan Deprest is this person who you told me earlier is one of the foremost experts regarding biocompatibility of meshes?

A. Exactly, yes.

Q. And you say, "It came up that there are two issues with Prolift: erosion and shrinkage." Right?

A. Yes, yes.

Q. So, again, there's this recurring issue of erosion and shrinkage with Prolift® which goes back all the way to the beginning that was issues that you knew you were going to deal with, with this product and this system. Correct?

MS. KABBASH: Objection.

THE WITNESS: Yes.

BY MR. SLATER:

Q. And it says, "Regarding erosions, whether a change in the mesh could result in any improvement is unknown as there is no certitude that the problem is mesh-related. It could as well be a surgical issue."

Again pointing out that you still don't have an understanding really of exactly what leads to mesh erosion? There's just theories?

A. Yes. We still don't have it in 2012.

Q. And then you say, "The responsibility of the mesh seems to be more established regarding" a "shrinkage and further to the expert's discussion,

it was speculated that Ultrapro could be a solution for this problem, which is less common but can be more severe than erosion."

And this was confirmed to you in the meeting with Jan Deprest who, again, you had said you have great respect for who's a worldwide authority. Correct?

A. Correct.

MR. SLATER: You can take that document down.

BY MR. SLATER:

Q. I'm handing you a document I've marked as exhibit -- wait a second. We may have just gone through that, so one second.

MR. SLATER: Go off the video for a second.

THE VIDEOGRAPHER: The time is now 5:45. We are going off the record.

- - -

(A discussion off the record occurred.)

- - -

(Deposition adjourned at approximately 5:48 p.m.)

CERTIFICATE

I, ANN MARIE MITCHELL, a Notary Public and Certified Court Reporter of the State of New Jersey, do hereby certify that prior to the commencement of the examination, AXEL ARNAUD, MD was duly sworn by me to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

____
ANN MARIE MITCHELL, CRR, RDR, CCR
Notary Number: 2356252
Notary Expiration: February 22, 2017
CCR Number: 30XI00212000

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I,_____________________, do hereby certify that I have read the foregoing pages, 1 - 302, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
AXEL ARNAUD, MD DATE

Subscribed and sworn
to before me this
_____ day of ______________, 20____.
My commission expires:______________

____
Notary Public